

## PenVe Analysis Results

1.1.	<i>Summary of Patient Status – Safety Population .....</i>	2
1.2.	<i>Summary of Demographic and Baseline Characteristics by Treatment – Intent-to-Treat Population .....</i>	3
1.3.	<i>Summary of Patient Preference – Intent-to-Treat Population .....</i>	6
1.4.	<i>Request for Formulation Change – Intent-to-Treat Population .....</i>	7
1.5.	<i>Summary of Adverse Events – Safety Population .....</i>	8
1.6.	<i>Number (%) of Adverse Events (AE) Reported by Patients in the Control Group by CTC Severity and Treatment Group – Safety Population .....</i>	9
1.7.	<i>Number (%) of Adverse Events (AE) Reported by Patients in the Treatment Group by CTC Severity and Treatment Group – Safety Population .....</i>	12
1.8.	<i>Summary of Patient Attendance: Number of Visits Attended by Patients – Intent-to-Treat Population .....</i>	15
1.9.	<i>Summary of Patient Attendance: Number of Telephone Calls Answered by Patients – Intent-to-Treat Population .....</i>	17
1.10.	<i>Summary of Patient Compliance: Comparison of Vitamin E levels at Baseline, 3 Months, and 6 Months – Intent-to-Treat Population .....</i>	24
1.11.	<i>Summary of Patient Compliance: Self-Reported Patient Adherence to Pentoxifylline and Vitamin E - Intent-to-Treat Population .....</i>	25
1.12.	<i>Number (%) of Questionnaires Completed by Participants by Treatment - Safety Population.....</i>	26
1.13.	<i>Secondary Outcome: Difference in Mouth Opening Measurements from Baseline to 6 Months Post Randomisation .....</i>	27
1.14.	<i>Secondary Outcome: Presence of Osteoradionecrosis (ORN) at 6 Months Post Randomisation by Treatment .....</i>	28
1.15.	<i>Secondary Outcome: Difference in Swallowing Scores from Baseline to 6 Months Post Randomisation .....</i>	29
1.16.	<i>Secondary Outcome: Difference in Quality-Of-Life Scores from Baseline to 6 Months Post Randomisation .....</i>	35

***1.1. Summary of Patient Status – Safety Population***

	Total (N=54)
<b>Number of Patients Consented n (%)</b>	54 (100%)
<b>Number of Eligible Patients n (%)</b>	53 (98.1%)
<b>Number of Patients Randomised n (%)</b>	29 (53.7%)
<b>Completers of the Study (a) n (%)</b>	22 (40.7%)

Note: N = number of patients consented, n = Number of subjects in the specified category with non-missing values.

(a) Completers for study are defined as patients who attended their 6-month post randomisation assessment>.

***1.2. Summary of Demographic and Baseline Characteristics by Treatment – Intent-to-Treat Population***

	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Total (N=29)
<b>Age (years)</b>			
N	7	22	29
Mean (SD)	56.9 (6.64)	59.3 (8.60)	58.7 (8.12)
Median	55.0	60.3	60.1
Min, Max	50.8, 68.8	40.6, 74.2	40.6, 74.2
<b>Sex n (%)</b>			
Male	6 (85.7%)	18 (81.8%)	24 (82.8%)
Female	1 (14.3%)	4 (18.2%)	5 (17.2%)
<b>Ethnicity n (%)</b>			
White	6 (85.7%)	18 (81.8%)	24 (82.8%)
Asian	0 (0%)	1 (4.5%)	1 (3.4%)
Black	0 (0%)	1 (4.5%)	1 (3.4%)
Mixed	0 (0%)	0 (0%)	0 (0%)
Other	1 (14.3%)	2 (9.1%)	3 (10.3%)
Missing	0 (0%)	0 (0%)	0 (0%)
<b>Education n (%)</b>			
None	0 (0%)	1 (4.5%)	1 (3.4%)
Secondary (GCSE or equivalent)	1 (14.3%)	7 (31.8%)	8 (27.6%)
Further (A level or equivalent)	2 (28.6%)	4 (18.2%)	6 (20.7%)

	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Total (N=29)
Higher (Degree or equivalent)	3 (42.9%)	8 (36.4%)	11 (37.9%)
Vocational	1 (14.3%)	2 (9.1%)	3 (10.3%)
Missing	0 (0%)	0 (0%)	0 (0%)
<b>Employment n (%)</b>			
No	2 (28.6%)	9 (40.9%)	11 (37.9%)
Yes	5 (71.4%)	12 (54.5%)	17 (58.6%)
Missing	0 (0%)	1 (4.5%)	1 (3.4%)
<b>Index of Multiple Deprivation (IMD) Score</b>			
N	6	22	28
Mean (SD)	36.9 (7.35)	19.4 (10.9)	23.1 (12.5)
Median	38.1	19.6	22.5
Min, Max	23.5, 45.7	2.46, 38.1	2.46, 45.7
Missing	1 (14.3%)	0 (0%)	1 (3.4%)
<b>Smoking Status Prior to Cancer Diagnosis n (%)</b>			
Current smoker	1 (14.3%)	2 (9.1%)	3 (10.3%)
Ex-smoker	4 (57.1%)	15 (68.2%)	19 (65.5%)
Never smoked	2 (28.6%)	5 (22.7%)	7 (24.1%)
Missing	0 (0%)	0 (0%)	0 (0%)
<b>Type of Head and Neck Cancer n (%)</b>			
Oropharynx (Tonsil, Base of Tongue)	4 (57.1%)	14 (63.6%)	18 (62.1%)
Nasopharynx	2 (28.6%)	1 (4.5%)	3 (10.3%)
Oral cavity	0 (0%)	3 (13.6%)	3 (10.3%)

	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Total (N=29)
Maxillary sinus	0 (0%)	1 (4.5%)	1 (3.4%)
Salivary glands	1 (14.3%)	2 (9.1%)	3 (10.3%)
Unknown primary of the neck	0 (0%)	0 (0%)	0 (0%)
Hypopharynx	0 (0%)	1 (4.5%)	1 (3.4%)
Not applicable	0 (0%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	0 (0%)

#### **Oncology Treatment n (%)**

Radiotherapy	0 (0%)	1 (4.5%)	1 (3.4%)
Radiotherapy and chemotherapy	6 (85.7%)	16 (72.7%)	22 (75.9%)
Radiotherapy and surgery	1 (14.3%)	3 (13.6%)	4 (13.8%)
Radiotherapy and chemotherapy and surgery	0 (0%)	2 (9.1%)	2 (6.9%)
Not applicable	0 (0%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	0 (0%)

Note: N = number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values.

Abbreviation: SD = Standard Deviation.

### ***1.3. Summary of Patient Preference – Intent-to-Treat Population***

	Pentoxifylline & Vitamin E (N=22)
<b>Preference for Pentoxifylline n (%)</b>	
Liquid	2 (9.1%)
Tablet	13 (59.1%)
No preference	0 (0%)
Don't know	0 (0%)
Not applicable	1 (4.5%)
Missing	6 (27.3%)
<b>Preference for Vitamin E n (%)</b>	
Liquid	2 (9.1%)
Tablet	13 (59.1%)
No preference	0 (0%)
Don't know	0 (0%)
Not applicable	1 (4.5%)
Missing	6 (27.3%)

Note: n = Number of subjects in the specified category with non-missing values

***1.4. Request for Formulation Change – Intent-to-Treat Population***

	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Total (N=29)
<b>Requested formulation change for Pentoxifylline or Vitamin E n (%)</b>			
Yes	0 (0%)	0 (0%)	0 (0%)
No, never requested to change formulation during trial	0 (0%)	22 (100%)	22 (75.9%)
No, participant is not in intervention arm	5 (71.4%)	0 (0%)	5 (17.2%)
Not applicable	2 (28.6%)	0 (0%)	2 (6.9%)
Missing	0 (0%)	0 (0%)	0 (0%)

Note: n = Number of subjects in the specified category with non-missing values

### ***1.5. Summary of Adverse Events – Safety Population***

	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Total (N=29)
<b>Patients with any Adverse Event</b>	1 (14.3%)	11 (50%)	12 (41.4%)
<b>Patients with any Serious Adverse Event</b>	0 (0%)	1 (4.5%)	1 (3.4%)
<b>Patients with any Treatment Emergent Adverse Event (TEAE)</b>	1 (14.3%)	11 (50%)	12 (41.4%)
<b>Patients Withdrawn from Treatment due to Adverse Event</b>	0 (0%)	0 (0%)	0 (0%)

Note: Percentage (%) based on number of patients in the row category/N within the column category.

Treatment emergent adverse event is defined as any event that occurs on or after the first dose of study drug administration or any pre-existing event which worsened in severity after dosing.



**1.6. Number (%) of Adverse Events (AE) Reported by Patients in the Control Group  
by CTC Severity and Treatment Group – Safety Population**

System Organ Class Preferred Term	Control (N=7)		
	Mild	Moderate	Severe
<b>All Adverse Events</b>	1 (100.0)	0 ( 0.0)	0 ( 0.0)
<b>Cardiovascular</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Atrial flutter	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Endocrine</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Under active thyroid	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Eyes, ear, nose, throat</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Cough	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Difficulty swallowing	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Dry throat	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Grazed throat	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Gastric irritation</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
No description	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Neoplasia</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Recurrent cancer	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Neurological</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Dizziness	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Headache	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Migraine	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Tingling in the leg	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Other</b>	1 (100.0)	0 ( 0.0)	0 ( 0.0)

System Organ Class Preferred Term	Control (N=7)		
	Mild	Moderate	Severe
Body pain	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
COVID Positive	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Dizziness	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Dry mouth	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Fever	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Gurgling stomach	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Head and Neck scan	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Low saliva	1 (100.0)	0 ( 0.0)	0 ( 0.0)
Mouth feels hot and dry	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Negative COVID test	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Ng tube came out through mouth	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Phlegm	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Shaking	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
shortness in breathing	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Sore oesophagus	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
sore stiff jaw	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Sore tongue and throat	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Ulcer on roof of mouth	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Ulcer on tongue	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
X-ray to guide Ng tube back in	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Other gastro-intestinal</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Constipation	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Diarrhoea	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Nausea	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Stomach ache	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Stomach ache right side	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)

System Organ Class Preferred Term	Control (N=7)		
	Mild	Moderate	Severe
Vomiting	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Vomiting after morning dose of IMP	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Vomiting evening after IMP	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Psychological</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Depression	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
<b>Respiratory</b>	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Chest Infection	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Common cold	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)

Note: Adverse event (AE) is defined as any event that occurs on or after the first dose of study drug administration or any pre-existing event which worsened in severity after dosing.

If a patient experiences adverse events within the same SOC and PT at different severity levels, only the worst severity will be presented for that SOC and PT.

**1.7. Number (%) of Adverse Events (AE) Reported by Patients in the Treatment Group by CTC Severity and Treatment Group – Safety Population**

System Organ Class Preferred Term	Pentoxifylline & Vitamin E (N=22)		
	Mild	Moderate	Severe
<b>All Adverse Events</b>	47 ( 73.4)	11 ( 17.2)	6 ( 9.4)
<b>Cardiovascular</b>	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Atrial flutter	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
<b>Endocrine</b>	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)
Under active thyroid	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)
<b>Eyes, ear, nose, throat</b>	2 ( 3.1)	1 ( 1.6)	1 ( 1.6)
Cough	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)
Difficulty swallowing	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Dry throat	0 ( 0.0)	0 ( 0.0)	1 ( 1.6)
Grazed throat	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
<b>Gastric irritation</b>	4 ( 6.2)	0 ( 0.0)	0 ( 0.0)
No description	4 ( 6.2)	0 ( 0.0)	0 ( 0.0)
<b>Neoplasia</b>	0 ( 0.0)	0 ( 0.0)	1 ( 1.6)
Recurrent cancer	0 ( 0.0)	0 ( 0.0)	1 ( 1.6)
<b>Neurological</b>	10 ( 15.6)	3 ( 4.7)	0 ( 0.0)
Dizziness	5 ( 7.8)	1 ( 1.6)	0 ( 0.0)
Headache	5 ( 7.8)	1 ( 1.6)	0 ( 0.0)
Migraine	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)
Tingling in the leg	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
<b>Other</b>	13 ( 20.3)	4 ( 6.2)	4 ( 6.2)

System Organ Class Preferred Term	Pentoxifylline & Vitamin E (N=22)		
	Mild	Moderate	Severe
Body pain	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)
COVID Positive	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)
Dizziness	5 ( 7.8)	1 ( 1.6)	0 ( 0.0)
Dry mouth	1 ( 1.6)	0 ( 0.0)	1 ( 1.6)
Fever	0 ( 0.0)	0 ( 0.0)	1 ( 1.6)
Gurgling stomach	0 ( 0.0)	2 ( 3.1)	0 ( 0.0)
Head and Neck scan	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Low saliva	0 ( 0.0)	0 ( 0.0)	0 ( 0.0)
Mouth feels hot and dry	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Negative COVID test	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Ng tube came out through mouth	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Phlegm	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Shaking	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
shortness in breathing	0 ( 0.0)	0 ( 0.0)	1 ( 1.6)
Sore oesophagus	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
sore stiff jaw	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Sore tongue and throat	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Ulcer on roof of mouth	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Ulcer on tongue	0 ( 0.0)	0 ( 0.0)	1 ( 1.6)
X-ray to guide Ng tube back in	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
<b>Other gastro-intestinal</b>	<b>14 ( 21.9)</b>	<b>2 ( 3.1)</b>	<b>0 ( 0.0)</b>
Constipation	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Diarrhoea	1 ( 1.6)	1 ( 1.6)	0 ( 0.0)
Nausea	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Stomach ache	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Stomach ache right side	0 ( 0.0)	1 ( 1.6)	0 ( 0.0)

System Organ Class Preferred Term	Pentoxifylline & Vitamin E (N=22)		
	Mild	Moderate	Severe
Vomiting	8 ( 12.5)	0 ( 0.0)	0 ( 0.0)
Vomiting after morning dose of IMP	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Vomiting evening after IMP	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Psychological	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Depression	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Respiratory	2 ( 3.1)	0 ( 0.0)	0 ( 0.0)
Chest Infection	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)
Common cold	1 ( 1.6)	0 ( 0.0)	0 ( 0.0)

Note: Adverse event (AE) is defined as any event that occurs on or after the first dose of study drug administration or any pre-existing event which worsened in severity after dosing.

If a patient experiences adverse events within the same SOC and PT at different severity levels, only the worst severity will be presented for that SOC and PT.

***1.8. Summary of Patient Attendance: Number of Visits Attended by Patients – Intent-to-Treat Population***

	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Total (N=29)
<b>Visit 1</b>			
Absent	0 (0%)	0 (0%)	0 (0%)
Present	7 (100%)	22 (100%)	29 (100%)
<b>Visit 2</b>			
Absent	0 (0%)	0 (0%)	0 (0%)
Present	7 (100%)	22 (100%)	29 (100%)
<b>Visit 3</b>			
Absent	0 (0%)	0 (0%)	0 (0%)
Present	7 (100%)	22 (100%)	29 (100%)
<b>Visit 4</b>			
Absent	1 (14.3%)	1 (4.5%)	2 (6.9%)
Present	6 (85.7%)	21 (95.5%)	27 (93.1%)
<b>Visit 5</b>			
Absent	1 (14.3%)	3 (13.6%)	4 (13.8%)
Present	6 (85.7%)	19 (86.4%)	25 (86.2%)

	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Total (N=29)
<b>Visit 6</b>			
Absent	0 (0%)	0 (0%)	0 (0%)
Present	7 (100%)	22 (100%)	29 (100%)

Note: N = Number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values



***1.9. Summary of Patient Attendance: Number of Telephone Calls Answered by Patients – Intent-to-Treat Population***

	Pentoxifylline & Vitamin E (N=22)
<b>Day 1</b>	
Study team contacted participant - Successful	19 (86.4%)
Study team contacted participant - Not successful	0 (0%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)
<b>Day 2</b>	
Study team contacted participant - Successful	18 (81.8%)
Study team contacted participant - Not successful	1 (4.5%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)
<b>Day 3</b>	
Study team contacted participant - Successful	19 (86.4%)
Study team contacted participant - Not successful	0 (0%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)

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Pentoxifylline & Vitamin E  
(N=22)

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**Day 4**

Study team contacted participant - Successful	19 (86.4%)
Study team contacted participant - Not successful	0 (0%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)

**Day 5**

Study team contacted participant - Successful	19 (86.4%)
Study team contacted participant - Not successful	0 (0%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)

**Day 6**

Study team contacted participant - Successful	17 (77.3%)
Study team contacted participant - Not successful	2 (9.1%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)

**Day 7**

Study team contacted participant - Successful	19 (86.4%)
Study team contacted participant - Not successful	0 (0%)
Participant contacted study team	0 (0%)

	Pentoxifylline & Vitamin E (N=22)
Not applicable	0 (0%)
Missing	3 (13.6%)
<b>Day 8</b>	
Study team contacted participant - Successful	18 (81.8%)
Study team contacted participant - Not successful	1 (4.5%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)
<b>Day 9</b>	
Study team contacted participant - Successful	17 (77.3%)
Study team contacted participant - Not successful	2 (9.1%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)
<b>Day 10</b>	
Study team contacted participant - Successful	19 (86.4%)
Study team contacted participant - Not successful	0 (0%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	3 (13.6%)

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Pentoxifylline & Vitamin E  
(N=22)

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**Day 11**

Study team contacted participant - Successful	17 (77.3%)
Study team contacted participant - Not successful	1 (4.5%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	4 (18.2%)

**Day 12**

Study team contacted participant - Successful	16 (72.7%)
Study team contacted participant - Not successful	2 (9.1%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	4 (18.2%)

**Day 13**

Study team contacted participant - Successful	17 (77.3%)
Study team contacted participant - Not successful	1 (4.5%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	4 (18.2%)

**Day 14**

Study team contacted participant - Successful	17 (77.3%)
Study team contacted participant - Not successful	1 (4.5%)
Participant contacted study team	0 (0%)

	Pentoxifylline & Vitamin E (N=22)
Not applicable	0 (0%)
Missing	4 (18.2%)
<b>Week 5</b>	
Study team contacted participant - Successful	15 (68.2%)
Study team contacted participant - Not successful	3 (13.6%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	4 (18.2%)
<b>Week 8</b>	
Study team contacted participant - Successful	14 (63.6%)
Study team contacted participant - Not successful	2 (9.1%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	6 (27.3%)
<b>Week 11</b>	
Study team contacted participant - Successful	14 (63.6%)
Study team contacted participant - Not successful	2 (9.1%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	6 (27.3%)

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Pentoxifylline & Vitamin E  
(N=22)

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**Week 14**

Study team contacted participant - Successful	11 (50.0%)
Study team contacted participant - Not successful	5 (22.7%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	6 (27.3%)

**Week 17**

Study team contacted participant - Successful	10 (45.5%)
Study team contacted participant - Not successful	3 (13.6%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	9 (40.9%)

**Week 20**

Study team contacted participant - Successful	10 (45.5%)
Study team contacted participant - Not successful	3 (13.6%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	9 (40.9%)

**Week 23**

Study team contacted participant - Successful	9 (40.9%)
Study team contacted participant - Not successful	2 (9.1%)
Participant contacted study team	0 (0%)

	Pentoxifylline & Vitamin E (N=22)
Not applicable	0 (0%)
Missing	11 (50.0%)

## Week 26

Study team contacted participant - Successful	5 (22.7%)
Study team contacted participant - Not successful	2 (9.1%)
Participant contacted study team	0 (0%)
Not applicable	0 (0%)
Missing	15 (68.2%)

Note: N = Number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values

**1.10. Summary of Patient Compliance: Comparison of Vitamin E levels at Baseline, 3 Months, and 6 Months – Intent-to-Treat Population**

	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Total (N=29)
<b>Baseline</b>			
N	7	21	28
Mean (SD)	29.6 (7.34)	35.2 (10.6)	33.8 (10.1)
Median	26.9	34.2	32.4
Min, Max	22.2, 43.8	16.0, 59.3	16.0, 59.3
Missing	0 (0%)	1 (4.5%)	1 (3.4%)
<b>Month 3</b>			
N	6	16	22
Mean (SD)	31.8 (5.36)	91.8 (184)	75.4 (158)
Median	31.8	45.4	38.6
Min, Max	22.8, 38.1	26.3, 778	22.8, 778
Missing	1 (14.3%)	6 (27.3%)	7 (24.1%)
<b>Month 6</b>			
N	5	15	20
Mean (SD)	31.6 (8.41)	55.2 (22.3)	49.3 (22.1)
Median	33.6	46.2	42.7
Min, Max	22.1, 43.1	27.0, 91.5	22.1, 91.5
Missing	2 (28.6%)	7 (31.8%)	9 (31.0%)

Note: N = Number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values



**1.11. Summary of Patient Compliance: Self-Reported Patient Adherence to Pentoxifylline and Vitamin E - Intent-to-Treat Population**

	Pentoxifylline & Vitamin E (N=22)
<b>Number of missed Vitamin E doses n (%)</b>	
N	10.0
Mean (SD)	0.455 (0.963)
Min, Max	0, 3.00
<b>Number of missed Pentoxifylline doses n (%)</b>	
N	25.0
Mean (SD)	1.14 (1.81)
Min, Max	0, 6.00

Note: N = number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values.

Number of missed doses are reported whilst the patient is enrolled in the study. If a patient discontinued, they are not deemed to have missed a dose post discontinuation

**1.12. Number (%) of Questionnaires Completed by Participants by Treatment - Safety Population**

	Baseline		Month 3		Month 6	
	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)
<b>University of Washington Quality of Life Questionnaire (UW-QOL) n (%)</b>						
Incomplete	2 (28.6%)	4 (18.2%)	2 (28.6%)	6 (27.3%)	2 (28.6%)	10 (45.5%)
Complete	5 (71.4%)	18 (81.8%)	5 (71.4%)	16 (72.7%)	5 (71.4%)	12 (54.5%)
<b>Sydney Swallow Questionnaire (SSQ) n (%)</b>						
Incomplete	0 (0%)	2 (9.1%)	1 (14.3%)	9 (40.9%)	1 (14.3%)	8 (36.4%)
Complete	7(100%)	20 (90.9%)	6 (85.7%)	13 (59.1%)	6 (85.7%)	14 (63.6%)

Note: N = Number of patients randomised in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values.

**1.13. Secondary Outcome: Difference in Mouth Opening Measurements from Baseline to 6 Months Post Randomisation**

	Baseline		Month 3		Month 6	
	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)
<b>Was measurement of trismus done? n (%)</b>						
Yes	7 (100%)	22 (100%)	6 (85.7%)	16 (72.7%)	5 (71.4%)	15 (68.2%)
No - Mouth too sore/painful	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
No - Other Reason	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	1 (14.3%)	2 (9.1%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Measurement of Trismus (mm)</b>						
N	7	22	6	16	5	15
Mean (SD)	111 (7.20)	114 (23.8)	114 (11.4)	116 (22.6)	114 (10.9)	120 (17.6)
Median	110	120	111	121	109	124
Min, Max	104, 125	45.0, 146	102,132	64.0, 144	105, 127	85.0, 145
Missing	0 (0%)	0 (0%)	1 (14.3%)	6 (27.3%)	2 (28.6%)	7 (31.8%)

Note: N = number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values.

Abbreviation: SD = Standard Deviation.

**1.14. Secondary Outcome: Presence of Osteoradionecrosis (ORN) at 6 Months Post Randomisation by Treatment**

	Baseline		Month 3		Month 6	
	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)
<b>Was the oral examination done? n (%)</b>						
Yes	7 (100%)	22 (100%)	6 (85.7%)	16 (72.7%)	5 (71.4%)	15 (68.2%)
No - Mouth too sore/painful	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
No - Other Reason	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	1 (14.3%)	2 (9.1%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Presence of osteoradionecrosis (ORN) n (%)</b>						
Present	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Absent	7 (100%)	22 (100%)	6 (85.7%)	15 (68.2%)	5 (71.4%)	15 (68.2%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	6 (27.3%)	2 (28.6%)	7(31.8%)

Note: N = number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values.

Abbreviation: SD = Standard Deviation.

**1.15. Secondary Outcome: Difference in Swallowing Scores from Baseline to 6 Months Post Randomisation**

	Baseline		Month 3		Month 6	
	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)

**How much difficulty  
do you have  
swallowing at  
present? (mm)**

N	7	22	6	16	6	17
Mean (SD)	14.6 (18.0)	22.0 (26.9)	13.0 (12.5)	20.3 (27.9)	18.2 (18.1)	20.4 (25.0)
Median	4.00	8.00	8.00	5.50	11.0	9.00
Min, Max	0, 40.0	0, 88.0	2.00, 29.0	0, 85.0	2.00, 50.0	0, 70.0
Missing	0 (0%)	0 (0%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	5 (22.7%)

**How much difficulty  
do you have  
swallowing THIN  
liquids? (eg: tea, soft  
drink, beer, coffee)  
(mm)**

N	7	22	6	16	6	17
Mean (SD)	6.00 (8.23)	10.1 (21.4)	1.50 (1.64)	9.69 (18.4)	6.83 (10.2)	9.41 (19.4)
Median	4.00	3.00	1.00	2.50	4.00	3.00
Min, Max	0, 24.0	0, 90.0	0, 4.00	0, 66.0	0, 27.0	0, 70.0
Missing	0 (0%)	0 (0%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	5 (22.7%)

**How much difficulty  
do you have  
swallowing THICK  
liquids? (eg:  
milkshakes, soups,  
custard) (mm)**

N	7	22	6	16	6	17
Mean (SD)	10.7 (14.2)	12.7 (22.3)	2.67 (3.08)	12.3 (22.7)	6.00 (8.02)	14.2 (24.7)
Median	4.00	4.00	2.00	2.50	3.50	5.00
Min, Max	0, 39.0	0, 89.0	0, 8.00	0, 69.0	0, 22.0	0, 79.0
Missing	0 (0%)	0 (0%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	5 (22.7%)

**How much difficulty do you have swallowing SOFT foods? (eg: mornays, scrambled egg, mashed potato) (mm)**

N	7	22	6	16	6	17
Mean (SD)	11.9 (17.0)	14.5 (23.5)	3.00 (2.83)	11.1 (18.5)	8.50 (10.9)	14.6 (21.1)
Median	4.00	3.50	2.50	5.00	4.00	6.00
Min, Max	0, 47.0	0, 89.0	0, 8.00	0, 71.0	1.00, 30.0	0, 79.0
Missing	0 (0%)	0 (0%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	5 (22.7%)

**How much difficulty do you have swallowing HARD foods? (eg: steak, raw fruit, raw vegetables) (mm)**

N	7	20	6	16	6	17
Mean (SD)	21.0 (30.9)	29.9 (33.1)	26.7 (23.6)	24.7 (33.8)	42.7 (39.4)	30.7 (34.0)
Median	5.00	14.5	18.5	5.50	42.5	12.0
Min, Max	0, 67.0	0, 98.0	3.00, 63.0	0, 99.0	3.00, 85.0	0, 100
Missing	0 (0%)	2 (9.1%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	5 (22.7%)

**How much difficulty do you have swallowing DRY foods? (eg: bread, biscuits, nuts) (mm)**

N	7	21	6	16	6	17
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Mean (SD)	20.7 (30.0)	29.2 (33.7)	37.8 (29.2)	37.8 (36.7)	36.2 (33.7)	40.4 (35.0)
Median	4.00	7.00	40.0	25.0	30.0	21.0
Min, Max	0, 73.0	0, 84.0	3.00, 81.0	0, 99.0	3.00, 76.0	0, 100
Missing	0 (0%)	1 (4.5%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	5 (22.7%)

**Do you have any difficulty swallowing your saliva? (mm)**

N	7	22	6	15	6	16
Mean (SD)	7.71 (14.4)	9.95 (20.4)	5.83 (10.0)	5.47 (4.42)	9.67 (18.9)	11.7 (19.5)
Median	2.00	3.50	2.50	5.00	2.50	5.50
Min, Max	0, 40.0	0, 85.0	0, 26.0	0, 13.0	0, 48.0	0, 77.0
Missing	0 (0%)	0 (0%)	1 (14.3%)	7 (31.8%)	1 (14.3%)	6 (27.3%)

**Do you have any difficulty starting a swallow? (mm)**

N	7	22	6	15	6	17
Mean (SD)	5.86 (8.75)	12.7 (24.2)	5.50 (6.35)	12.3 (23.5)	11.8 (19.9)	20.2 (25.4)
Median	1.00	4.00	3.50	3.00	4.50	9.00
Min, Max	0, 23.0	0, 85.0	0, 18.0	0, 77.0	0, 52.0	0, 81.0
Missing	0 (0%)	0 (0%)	1 (14.3%)	7 (31.8%)	1 (14.3%)	5 (22.7%)

**Do you ever have a feeling of food getting stuck in your throat when you swallow? (mm)**

N	7	22	6	15	6	17
Mean (SD)	10.3 (11.5)	21.5(31.3)	23.0(17.4)	22.7 (27.3)	29.0(25.3)	28.4 (28.5)
Median	4.00	4.00	19.0	10.0	25.5	14.0
Min, Max	1.00, 32.0	0, 93.0	4.00,49.0	0, 78.0	5.00, 75.0	0, 85.0
Missing	0 (0%)	0 (0%)	1 (14.3%)	7 (31.8%)	1 (14.3%)	5 (22.7%)

**Do you ever cough  
or choke when  
swallowing solid  
foods? (eg: bread,  
meat or fruit) (mm)**

N	7	19	6	15	6	17
Mean (SD)	14.3 (18.5)	14.7(25.2)	23.0 (24.4)	25.0 (36.4)	21.8 (27.1)	25.1 (30.7)
Median	4.00	4.00	13.0	6.00	13.5	14.0
Min, Max	1.00, 51.0	0, 91.0	4.00, 65.0	0, 94.0	3.00, 74.0	0, 87.0
Missing	0 (0%)	3 (13.6%)	1 (14.3%)	7 (31.8%)	1 (14.3%)	5 (22.7%)

**Do you ever cough  
or choke when  
swallowing liquids?  
(eg: coffee, tea,  
water, beer) (mm)**

N	7	22	6	14	6	17
Mean (SD)	5.43 (3.51)	12.7 (22.5)	12.0 (20.2)	11.3 (20.4)	13.0(24.1)	17.9(26.5)
Median	5.00	3.00	5.00	3.50	4.50	7.00
Min, Max	1.00, 11.0	0, 88.0	0, 53.0	0, 75.0	0, 62.0	0, 83.0
Missing	0 (0%)	0 (0%)	1 (14.3%)	8 (36.4%)	1 (14.3%)	5 (22.7%)

**How long does it  
take you to eat an  
average meal? n (%)**

Less than 15 minutes	2 (28.6%)	8 (36.4%)	0 (0%)	4 (18.2%)	0 (0%)	5 (22.7%)
About 15-30 minutes	3 (42.9%)	10 (45.5%)	5 (71.4%)	8 (36.4%)	4 (57.1%)	6 (27.3%)
About 30-45 minutes	2 (28.6%)	1 (4.5%)	1 (14.3%)	2 (9.1%)	2 (28.6%)	4 (18.2%)
About 45-60 minutes	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
More than 60 minutes	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)
Unable to swallow at all	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	1 (4.5%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	6 (27.3%)



**When you swallow  
does food or liquid  
go up behind your  
nose or come out of  
your nose? (mm)**

N	7	21	6	15	6	17
Mean (SD)	6.14 (10.9)	4.38 (12.2)	7.50 (14.6)	16.1 (28.0)	14.2 (26.4)	17.1 (30.1)
Median	1.00	2.00	2.00	3.00	4.00	5.00
Min, Max	0, 30.0	0, 57.0	0, 37.0	0, 94.0	1.00, 68.0	0, 85.0
Missing	0 (0%)	1 (4.5%)	1 (14.3%)	7 (31.8%)	1 (14.3%)	5 (22.7%)

**Do you ever need to  
swallow more than  
once for your food to  
go down? (mm)**

N	7	21	6	16	6	16
Mean (SD)	7.00 (7.39)	17.0 (26.6)	15.7 (14.7)	21.1 (30.6)	25.8 (25.3)	26.5 (33.2)
Median	4.00	4.00	10.5	6.50	19.0	9.50
Min, Max	0,20.0	0, 86.0	5.00,45.0	0,91.0	5.00, 74.0	0, 95.0
Missing	0 (0%)	1 (4.5%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	6 (27.3%)

**Do you ever cough  
up or spit out food  
or liquids DURING  
a meal? (mm)**

N	7	21	6	16	6	16
Mean (SD)	3.43 (6.68)	16.8 (29.6)	18.2 (19.0)	16.4 (27.8)	20.0 (23.8)	19.1 (28.8)
Median	0	3.00	11.0	3.50	12.0	5.00
Min, Max	0, 18.0	0, 90.0	1.00, 48.0	0, 84.0	3.00, 65.0	0, 83.0
Missing	0 (0%)	1 (4.5%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	6 (27.3%)

**How do you rate the  
severity of your  
swallowing problem  
today? (mm)**

N	7	21	6	16	6	16
Mean (SD)	19.7 (25.1)	24.8 (30.9)	17.0 (20.1)	16.4 (20.4)	24.3 (23.7)	23.2 (30.7)
Median	4.00	7.00	7.50	8.50	18.0	9.50
Min, Max	0, 63.0	0, 96.0	4.00, 55.0	0, 64.0	4.00, 64.0	0, 84.0
Missing	0 (0%)	1 (4.5%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	6 (27.3%)

**How much does  
your swallowing  
problem interfere  
with your enjoyment  
or quality of life?  
(mm)**

N	7	21	6	16	6	16
Mean (SD)	18.3 (26.5)	21.9 (31.5)	17.8 (18.9)	17.1 (23.7)	16.8 (19.8)	21.2 (31.0)
Median	5.00	6.00	13.0	7.00	9.50	6.50
Min, Max	0, 70.0	0, 94.0	4.00, 55.0	0, 90.0	3.00, 55.0	0, 83.0
Missing	0 (0%)	1 (4.5%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	6 (27.3%)

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Note: N = number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values.

Abbreviation: SD = Standard Deviation.

**1.16. Secondary Outcome: Difference in Quality-Of-Life Scores from Baseline to 6 Months Post Randomisation**

	Baseline		Month 3		Month 6	
	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)	Control (N=7)	Pentoxifylline & Vitamin E (N=22)
<b>Pain n (%)</b>						
I have no pain	3 (42.9%)	5 (22.7%)	1 (14.3%)	9 (40.9%)	4 (57.1%)	12 (54.5%)
There is mild pain not needing medication	0 (0%)	7 (31.8%)	5 (71.4%)	5 (22.7%)	1 (14.3%)	4 (18.2%)
I have moderate pain - requires regular medication (codeine or nonnarcotic)	4 (57.1%)	9 (40.9%)	0 (0%)	1 (4.5%)	1 (14.3%)	1 (4.5%)
I have severe pain controlled only by narcotics	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
I have severe pain, not controlled by medication	0 (0%)	1 (4.5%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Appearance n (%)</b>						
There is no change in my appearance	5 (71.4%)	10 (45.5%)	4 (57.1%)	7 (31.8%)	5 (71.4%)	9 (40.9%)
The change in my appearance is minor	1 (14.3%)	6 (27.3%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	4 (18.2%)
My appearance bothers me but I remain active	1 (14.3%)	6 (27.3%)	1 (14.3%)	4 (18.2%)	0 (0%)	3 (13.6%)
I feel significantly disfigured and limit my activities due to my appearance	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
I cannot be with people due to my	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

appearance

Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	6 (27.3%)

#### Activity n (%)

I am as active as I have ever been	3 (42.9%)	8 (36.4%)	2 (28.6%)	4 (18.2%)	3 (42.9%)	3 (13.6%)
There are times when I can't keep up my old pace, but not often	2 (28.6%)	9 (40.9%)	2 (28.6%)	8 (36.4%)	1 (14.3%)	10 (45.5%)
I am often tired and have slowed down my activities although I still get out	2 (28.6%)	5 (22.7%)	2 (28.6%)	4 (18.2%)	2 (28.6%)	4 (18.2%)
I don't go out because I don't have the strength	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
I am usually in bed or chair and don't leave home	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	2 (9.1%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	4 (18.2%)	1 (14.3%)	5 (22.7%)

#### Recreation n (%)

There are no limitations to recreation at home or away from home	4 (57.1%)	9 (40.9%)	2 (28.6%)	5 (22.7%)	3 (42.9%)	7 (31.8%)
There are a few things I can't do but I still get out and enjoy life	2 (28.6%)	11 (50.0%)	2 (28.6%)	10 (45.5%)	2 (28.6%)	8 (36.4%)
There are many times when I wish I could get out more, but I'm not up to it	1 (14.3%)	2 (9.1%)	2 (28.6%)	1 (4.5%)	0 (0%)	1 (4.5%)
There are severe limitations to what I can do, mostly I stay at home and watch TV	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (14.3%)	1 (4.5%)

I can't do anything enjoyable	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Swallowing n (%)</b>						
I can swallow as well as ever	4 (57.1%)	12 (54.5%)	2 (28.6%)	8 (36.4%)	3 (42.9%)	8 (36.4%)
I cannot swallow certain solid foods	3 (42.9%)	7 (31.8%)	4 (57.1%)	8 (36.4%)	3 (42.9%)	7 (31.8%)
I can only swallow liquid food	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)	0 (0%)	2(9.1%)
I cannot swallow because it 'goes down the wrong way' and chokes me	0 (0%)	2 (9.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Chewing n (%)</b>						
I can chew as well as ever	6 (85.7%)	15 (68.2%)	1 (14.3%)	9 (40.9%)	4 (57.1%)	6 (27.3%)
I can eat soft solids but cannot chew some foods	1 (14.3%)	5 (22.7%)	5 (71.4%)	7(31.8%)	2 (28.6%)	10 (45.5%)
I cannot even chew soft solids	0 (0%)	2 (9.1%)	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Speech n (%)</b>						
My speech is the same as always	5 (71.4%)	15 (68.2%)	4 (57.1%)	11 (50.0%)	3 (42.9%)	9 (40.9%)
I have difficulty saying some words, but I can be	2 (28.6%)	7 (31.8%)	2 (28.6%)	5 (22.7%)	3 (42.9%)	8 (36.4%)

understood over the phone						
Only my family and friends can understand me	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
I cannot be understood	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Shoulder n (%)</b>						
I have no problem with my shoulder	4 (57.1%)	13 (59.1%)	4 (57.1%)	9 (40.9%)	5 (71.4%)	11 (50.0%)
My shoulder is stiff, but it has not affected my activity or strength	3 (42.9%)	6 (27.3%)	2 (28.6%)	7(31.8%)	0 (0%)	5 (22.7%)
Pain or weakness in my shoulder has caused me to change my work	0 (0%)	3 (13.6%)	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)
I cannot work due to problems with my shoulder	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (14.3%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Taste n (%)</b>						
I can taste food normally	5 (71.4%)	15 (68.2%)	1 (14.3%)	3 (13.6%)	2 (28.6%)	2 (9.1%)
I can taste most foods normally	2 (28.6%)	3 (13.6%)	4 (57.1%)	7 (31.8%)	2 (28.6%)	7 (31.8%)
I can taste some foods	0 (0%)	4 (18.2%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	7 (31.8%)
I cannot taste any foods	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	1 (14.3%)	1 (4.5%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)

Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Saliva n (%)</b>						
My saliva is of normal consistency	5 (71.4%)	16 (72.7%)	2 (28.6%)	2 (9.1%)	2 (28.6%)	4 (18.2%)
I have less saliva than normal, but it is enough	2 (28.6%)	5 (22.7%)	2 (28.6%)	11 (50.0%)	3 (42.9%)	7 (31.8%)
I have too little saliva	0 (0%)	1 (4.5%)	2 (28.6%)	2 (9.1%)	1 (14.3%)	5 (22.7%)
I have no saliva	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	1 (4.5%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Mood n (%)</b>						
My mood is excellent and unaffected by my cancer	3 (42.9%)	5 (22.7%)	2 (28.6%)	5 (22.7%)	2 (28.6%)	9 (40.9%)
My mood is generally good and only occasionally affected by my cancer	1 (14.3%)	13 (59.1%)	2 (28.6%)	10 (45.5%)	2 (28.6%)	7 (31.8%)
I am neither in a good mood nor depressed about my cancer	2 (28.6%)	2 (9.1%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
I am somewhat depressed about my cancer	0 (0%)	2 (9.1%)	2 (28.6%)	0 (0%)	2 (28.6%)	1 (4.5%)
I am extremely depressed about my cancer	1 (14.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Anxiety n (%)</b>						

I am not anxious about my cancer	4 (57.1%)	1 (4.5%)	3 (42.9%)	3 (13.6%)	3 (42.9%)	6 (27.3%)
I am a little anxious about my cancer	2 (28.6%)	15 (68.2%)	3 (42.9%)	13 (59.1%)	2 (28.6%)	10 (45.5%)
I am anxious about my cancer	0 (0%)	3 (13.6%)	0 (0%)	0 (0%)	1 (14.3%)	0 (0%)
I am very anxious about my cancer.	1 (14.3%)	3 (13.6%)	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)

**Which issues have been the most important to you during the past 7 days? - Pain n (%)**

Yes	4 (57.1%)	9 (40.9%)	1 (14.3%)	3 (13.6%)	0 (0%)	1 (4.5%)
No	2 (28.6%)	12 (54.5%)	4 (57.1%)	13 (59.1%)	6 (85.7%)	15 (68.2%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	1 (14.3%)	1 (4.5%)	2 (28.6%)	5 (22.7%)	1 (14.3%)	6 (27.3%)

**Which issues have been the most important to you during the past 7 days? - Appearance n (%)**

Yes	1 (14.3%)	2 (9.1%)	0 (0%)	3 (13.6%)	0 (0%)	2 (9.1%)
No	5 (71.4%)	19 (86.4%)	6 (85.7%)	13 (59.1%)	6 (85.7%)	15 (68.2%)
Not Applicable	1 (14.3%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	1 (4.5%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)



**Which issues have been the most important to you during the past 7 days? - Activity n (%)**

Yes	2 (28.6%)	0 (0%)	2 (28.6%)	3 (13.6%)	2 (28.6%)	3 (13.6%)
No	5 (71.4%)	19 (86.4%)	4 (57.1%)	13 (59.1%)	4 (57.1%)	14 (63.6%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	3 (13.6%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)

**Which issues have been the most important to you during the past 7 days? - Recreation n (%)**

Yes	1 (14.3%)	0 (0%)	1 (14.3%)	0 (0%)	1 (14.3%)	1 (4.5%)
No	5 (71.4%)	18 (81.8%)	5 (71.4%)	16 (72.7%)	5 (71.4%)	15 (68.2%)
Not Applicable	1 (14.3%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	4 (18.2%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	6 (27.3%)

**Which issues have been the most important to you during the past 7 days? - Swallowing n (%)**

Yes	4 (57.1%)	7 (31.8%)	4 (57.1%)	4 (18.2%)	2 (28.6%)	6 (27.3%)
No	3 (42.9%)	12 (54.5%)	2 (28.6%)	12 (54.5%)	4 (57.1%)	11 (50.0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)

Missing	0 (0%)	3 (13.6%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Which issues have been the most important to you during the past 7 days? - Chewing n (%)</b>						
Yes	0 (0%)	3 (13.6%)	3 (42.9%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
No	7 (100%)	16 (72.7%)	3 (42.9%)	11 (50.0%)	4 (57.1%)	12 (54.5%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	3 (13.6%)	1 (14.3%)	5 (22.7%)	2 (28.6%)	5 (22.7%)
<b>Which issues have been the most important to you during the past 7 days? - Speech n (%)</b>						
Yes	1 (14.3%)	5 (22.7%)	0 (0%)	1 (4.5%)	0 (0%)	3 (13.6%)
No	6 (85.7%)	14 (63.6%)	6 (85.7%)	15 (68.2%)	6 (85.7%)	14 (63.6%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	3 (13.6%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)
<b>Which issues have been the most important to you during the past 7 days? - Shoulder n (%)</b>						
Yes	2 (28.6%)	1 (4.5%)	0 (0%)	1 (4.5%)	0 (0%)	2 (9.1%)
No	5 (71.4%)	18 (81.8%)	6 (85.7%)	15 (68.2%)	6 (85.7%)	15 (68.2%)

Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	3 (13.6%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)

**Which issues have been the most important to you during the past 7 days? - Taste n (%)**

Yes	0 (0%)	1 (4.5%)	0 (0%)	8 (36.4%)	1 (14.3%)	3 (13.6%)
No	7 (100%)	18 (81.8%)	6 (85.7%)	7 (31.8%)	5 (71.4%)	13 (59.1%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	3 (13.6%)	1 (14.3%)	6 (27.3%)	1 (14.3%)	6 (27.3%)

**Which issues have been the most important to you during the past 7 days? - Saliva n (%)**

Yes	0 (0%)	4 (18.2%)	2 (28.6%)	2 (9.1%)	2 (28.6%)	7 (31.8%)
No	7 (100%)	15 (68.2%)	4 (57.1%)	14 (63.6%)	4 (57.1%)	10 (45.5%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	3 (13.6%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)

**Which issues have been the most important to you during the past 7 days? - Mood n (%)**

Yes	1 (14.3%)	3 (13.6%)	3 (42.9%)	0 (0%)	0 (0%)	3 (13.6%)
No	6 (85.7%)	16 (72.7%)	3 (42.9%)	16 (72.7%)	6 (85.7%)	14 (63.6%)

Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	3 (13.6%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)

**Which issues have been the most important to you during the past 7 days? - Anxiety n (%)**

Yes	1 (14.3%)	10 (45.5%)	0 (0%)	1 (4.5%)	1 (14.3%)	1 (4.5%)
No	6 (85.7%)	10 (45.5%)	6 (85.7%)	15 (68.2%)	5 (71.4%)	16 (72.7%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	0 (0%)	2 (9.1%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	5 (22.7%)

**Compared to the month before you developed cancer, how would you rate your health-related quality of life?**

Much better	0 (0%)	6 (27.3%)	0 (0%)	1 (4.5%)	0 (0%)	2 (9.1%)
Somewhat better	0 (0%)	2 (9.1%)	0 (0%)	4 (18.2%)	1 (14.3%)	1 (4.5%)
About the same	5 (71.4%)	9 (40.9%)	3 (42.9%)	6 (27.3%)	3 (42.9%)	6 (27.3%)
Somewhat worse	1 (14.3%)	3 (13.6%)	3 (42.9%)	5 (22.7%)	2 (28.6%)	6 (27.3%)
Much worse	0 (0%)	2 (9.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	1 (14.3%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	7 (31.8%)

**In general, would you say your health-related quality of life during the past 7 days has been:**

Outstanding	1 (14.3%)	1 (4.5%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Very good	1 (14.3%)	6 (27.3%)	1 (14.3%)	3 (13.6%)	2 (28.6%)	7 (31.8%)
Good	3 (42.9%)	9 (40.9%)	2 (28.6%)	9 (40.9%)	1 (14.3%)	4 (18.2%)
Fair	1 (14.3%)	5 (22.7%)	3 (42.9%)	3 (13.6%)	2 (28.6%)	3 (13.6%)
Poor	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)	1 (14.3%)	1 (4.5%)
Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	1 (14.3%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	7 (31.8%)

**Considering everything in your life that contributes to your personal well-being, rate your overall quality of life during the past 7 days**

Outstanding	1 (14.3%)	1 (4.5%)	0 (0%)	1 (4.5%)	0 (0%)	1 (4.5%)
Very good	3 (42.9%)	9 (40.9%)	2 (28.6%)	3 (13.6%)	2 (28.6%)	7 (31.8%)
Good	1 (14.3%)	6 (27.3%)	1 (14.3%)	9 (40.9%)	2 (28.6%)	6 (27.3%)
Fair	1 (14.3%)	5 (22.7%)	3 (42.9%)	3 (13.6%)	1 (14.3%)	1 (4.5%)
Poor	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)	1 (14.3%)	0 (0%)
Very poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Not Applicable	0 (0%)	0 (0%)	0 (0%)	1 (4.5%)	0 (0%)	0 (0%)
Missing	1 (14.3%)	0 (0%)	1 (14.3%)	5 (22.7%)	1 (14.3%)	7 (31.8%)

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Note: N = number of patients in the treatment group analysis set, n = Number of subjects in the specified category with non-missing values.

Abbreviation: SD = Standard Deviation.