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Comparing benzydamine with placebo in the prevention of radiation-induced mucositis in head and neck cancer patients in Imam Hossein Hospital, Iran

Submission date
20/11/2009

Recruitment status
No longer recruiting

Registration date
18/02/2010

Overall study status
Completed

Last Edited
18/02/2010

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Benzydamine versus placebo in radiation-induced mucositis in patients with head and neck cancer: a phase II randomised controlled trial

Acronym
Gorgani II

Study objectives
Benzydamine can prevent radiation-induced mucositis in head and neck cancer patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Imam Hossein Hospital, Department of Radiation Oncology Ethics Committee approved on the 10th July 2009 (ref: 122)

Study design
Phase II randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Head and neck cancer/mucositis

Interventions
Patients will be randomised in two groups (placebo and benzydamine). Subjects were encouraged to brush their teeth at least twice daily, floss once daily, rinse as necessary with bland oral rinses (e.g., normal saline, sodium bicarbonate). Commercial mouthwashes (over the counter or prescription), chlorhexidine, or other agents to aid in oral hygiene were prohibited.

Oral rinsing with study treatments was initiated the day before RT and continued for 2 weeks after the end of RT. 15 ml for 2 minutes, 4 - 8 times daily before and during RT, and for 2 weeks after completion of RT. If burning or stinging occurred, dilution of the rinse with water at 1:1 or 1:2 was allowed. All bottles of study rinse were returned each week and the amount returned recorded.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Benzydamine

Primary outcome measure
Reducing mucositis, measured during treatment (from the first day of radiotherapy until one week after termination of radiotherapy)

Secondary outcome measures
1. Time to grade III mucositis
2. Time to grade IV mucositis
Measured during treatment (from the first day of radiotherapy until one week after termination of radiotherapy).

Overall study start date
10/06/2009

Completion date
10/04/2010

Eligibility

Key inclusion criteria
1. Male and non-pregnant female subjects aged 18 - 80 years
2. Diagnoses of head and neck malignancy
3. Total external beam radiotherapy (RT) dose of at least 5000 cGy via a megavoltage treatment with either a cobalt-60 or a linear accelerator
4. At least two oral mucosal sites included in the planned RT treatment volume

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
50 (25 in each arm)

Key exclusion criteria
1. Karnofsky performance status less than 80%
2. Hypersensitivity to benzydamine or typical nonsteroidal anti-inflammatory drugs (NSAIDs)
3. Had taken experimental drugs within 30 days of study start
4. Chronically took steroids, NSAIDs, or other analgesics for other medical conditions

Date of first enrolment
10/06/2009

Date of final enrolment
10/04/2010

Locations

Countries of recruitment
Iran

Study participating centre
Imam Hossein Hospital
Tehran
Iran
1617763141

Sponsor information

Organisation
Imam Hossein Hospital (Iran)

Sponsor details
Department of Radiation Oncology
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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/053qhtw56

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Imam Hossein Hospital (Iran)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration