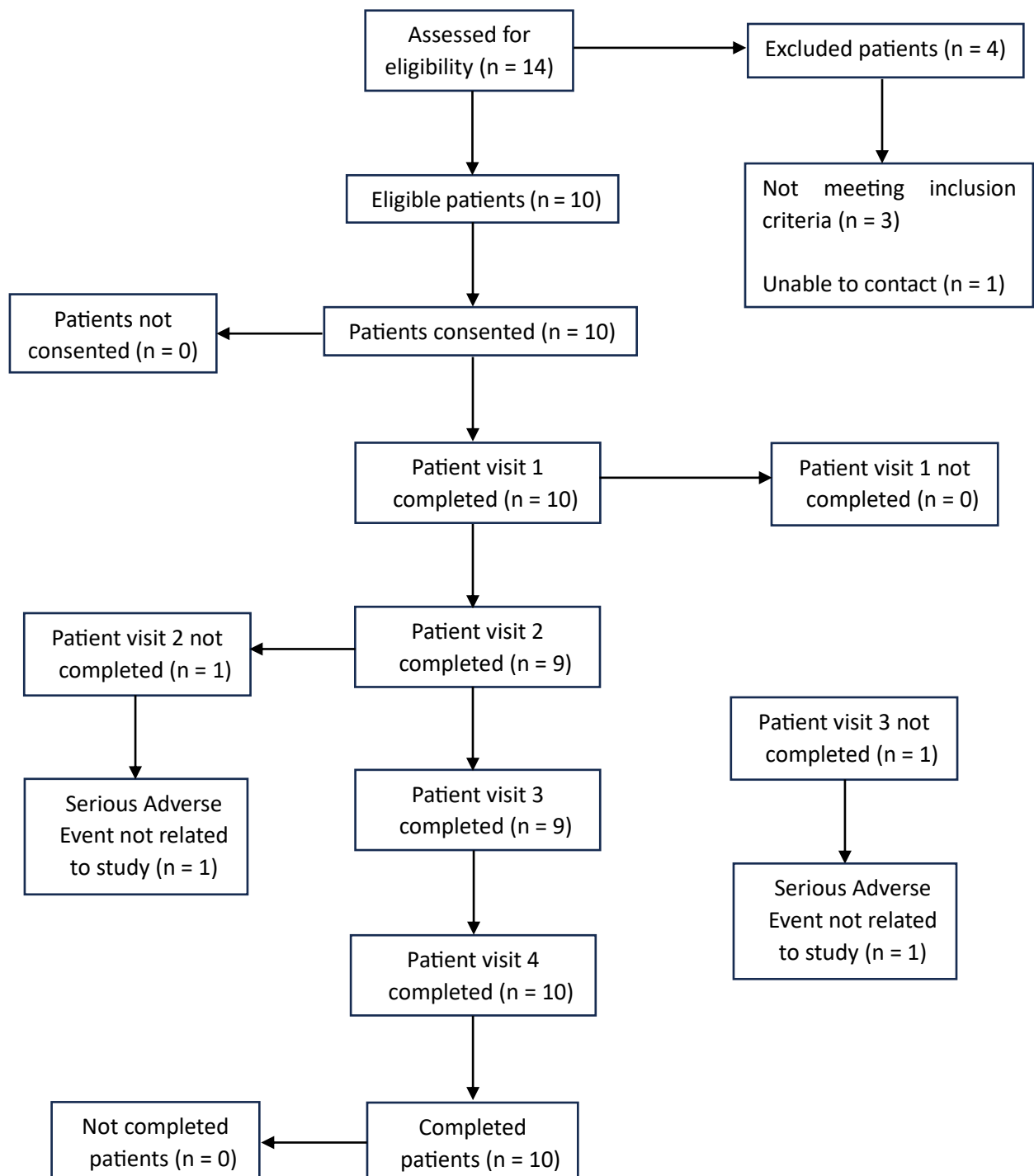


Study title: “Monitoring wound status using multiparameter optical fibre sensors”

Participant flow diagram



Baseline characteristics

	Variable	Statistics	Value
Demographic data	Patient	n	10
	Age (years)	Mean (SD)	57.6 (10.70)
		Median	59.5
		Min, Max	39,75
	Gender	Female	30% (3/10)
		Male	70% (7/10)
	Type of diabetes	I	10% (1/10)
		II	90% (9/10)
		Other	0%
	Age of onset (years)	Mean (SD)	33.4 (11.98)
Median		31	
Min, Max		15, 52	
Foot vascular and neurological test	Peripheral pulse palpation present	Dorsalis pedis, left	80% (8/10)
		Dorsalis pedis, right	80% (8/10)
		Posterior tibial, left	90% (9/10)
		Posterior tibial, right	90% (9/10)
	Ankle brachial pressure index (ABPI)	Mean (SD)	1.06 (0.2)
		Median	0.98
		Min, Max	0.90, 1.60
	10g monofilament detected	Hallux, left	0%
		Hallux, right	0%
		1 st metatarsal, left	0%
		1 st metatarsal, right	0%
		2 nd metatarsal, left	0%
		2 nd metatarsal, right	0%
		3 rd metatarsal, left	0%
3 rd metatarsal, right		0%	

Baseline characteristics (*continued*)

	Variable	Statistics	Value
Laboratory tests	HBA1C (mmols)	Mean (SD)	78.3 (13.16)
		Median	76.5
		Min, Max	60, 104
	EGFR (mL/min/1.73m ²)	Mean (SD)	78.25 (21.72)
		Median	88
		Min, Max	22, 90
Foot characteristics: ulcer description & ulcer area	Site of ulcer	Fore foot, left	40% (4/10)
		Fore foot, right	50% (5/10)
		Rear foot, left	0%
		Rear foot, right	0%
		Dorsal, left	0%
		Dorsal, right	0%
		Plantar, left	20% (2/10)
		Plantar, right	20% (2/10)
		Heel, left	0%
		Heel, right	0%
	Assessment of infection: IDSA criteria	Uninfected	90% (9/10)
		Mild infection	0%
		Moderate infection	10% (1/10)
		Severe infection	0%
	Measurement with silhouette wound imaging camera	Area (cm ²) mean, SD	1.89, 1.92
		Area (cm ²) median	1.15
		Area (cm ²) min, max	0.4, 7
		Depth (mm) mean, SD	2.3, 0.9
		Depth (mm) median	2
		Depth (mm) min, max	1, 4
Pain score	Visual Analogue Scale (VAS)	Mean, SD	8.1, 22.37
		Median	0
		Min, Max	0, 75

Outcome results

1. Primary outcomes

Participants screened	Participants consented	Reasons for not participating	
		Not meeting inclusion criteria	Unable to contact
14	10	3	1

Number of patients where measurements were taken with optical probe from wound surface

	Temperature	Relative Humidity	Ammonia	Carbon dioxide
Visit 1	10 / 10	10 / 10	10 / 10	10 / 10
Visit 2	9 / 10	9 / 10	9 / 10	9 / 10
Visit 3	9 / 10	9 / 10	9 / 10	9 / 10
Visit 4	10 / 10	10 / 10	10 / 10	10 / 10

2. Secondary outcomes

Wound size (cm²) measured as per normal clinical care with a Silhouette wound assessment camera (Entec Health Ltd)

	Mean	SD	Median	Min.	Max.
Visit 1	1.89	1.92	1.15	0.4	7
Visit 2	1.78	1.79	1.3	0.3	6
Visit 3	1.59	1.99	1	0.3	7
Visit 4	1.23	1.51	0.6	0	5

Incidence of secondary infection measured using assessment of ulcer infection by IDSA criteria

IDSA criteria	Visit 1	Visit 2	Visit 3	Visit 4
0 = None	9 / 10	8 / 9	8 / 9	8 / 10
1 = Mild [limited to skin and subcutaneous tissues and with inflammation limited to within 2cm of wound margin]	0 / 10	0 / 9	0 / 9	0 / 10
2 = Moderate [deeper and/or with more extensive inflammation]	1 / 10	1 / 9	1 / 9	1 / 10
3 = Severe [with systemic symptoms and signs]	0 / 10	0 / 9	0 / 9	1 / 10

Pain in the area of the ulcer assessed by patient-completed 100 mm Visual Analogue Scale (VAS) at the start of each patient visit

	Mean	SD	Median	Min.	Max.
Visit 1	8.10	22.37	0	0	75
Visit 2	10.22	23.11	0	0	75
Visit 3	21.56	31.08	0	0	74
Visit 4	11.11	21.82	0	0	70

Adverse events

Date of SAE onset	SAE description	Related to study	Action taken
14/08/2023	Patient admitted to hospital and was treated for infection	No	Subject continued in the trial once discharged from hospital, although trial visit 2 was missed.
06/03/2024	Patient admitted to hospital and was treated for infection and toe removed	No	Subject continued in the trial once discharged from hospital, although trial visit 3 was missed.