Prospective randomised trial comparing traditional suture technique with the sliding loop suture technique in the closure of surgical wounds in the foot and ankle area

Submission date 28/09/2007	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 28/09/2007	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 15/02/2012	Condition category Surgery	Individual participant data

Plain English summary of protocol Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Mr Christopher Walker

Contact details

Orthopaedic Directorate RLUH Prescott Street Liverpool United Kingdom L7 8XP +44 0151 706 3440 Christopher.Walker@rlbuht.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0207182916

Study information

Scientific Title

Study objectives To study if closure of a surgical wound in the foot or ankle, using a new technique is faster and more comfortable.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design 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 Surgery: Foot and ankle

Interventions

Half of the wounds length will be sutured using the traditional closing technique (control part) and the other half using the traction loop technique. The sutures will be removed in the outpatients department by an experienced nurse clinician. Prior to suture removal a junior nurse will open an envelope to indicate the part of the wound from where the suture removal will start. A junior doctor who will have no participation in the suture removal process will prepare the envelopes. A curtain will be placed, to ensure the patient has no visual contact with the wound during suture removal. A junior staff nurse or nursing student will be timing suture removal for each part of the wound. Pain during suture removal will be recorded using a 10 point visual analogue scale. Immediately after each part of the wound has been dealt with, patients will be recording their pain, using a specially designed form, without any visual contact between patients and the nurse clinician.

Intervention Type Procedure/Surgery

Phase Not Specified

Primary outcome measure Time and patient discomfort to remove sutures from the surgical wound.

Secondary outcome measures Not provided at time of registration

Overall study start date 01/03/2006

Completion date 01/03/2008

Eligibility

Key inclusion criteria Sixty eligible adult patients undergoing foot or ankle elective surgery.

Participant type(s) Patient

Age group Adult

Sex Not Specified

Target number of participants 60

Key exclusion criteria Not provided at time of registration

Date of first enrolment 01/03/2006

Date of final enrolment 01/03/2008

Locations

Countries of recruitment England

United Kingdom

Study participating centre Orthopaedic Directorate Liverpool United Kingdom L7 8XP

Sponsor information

Organisation Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Government

Funder Name Royal Liverpool and Broadgreen University Hospitals Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2003		Yes	No