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A prospective controlled trial comparing silicone and polyvinyl chloride (PVC) closed system wound drains

Submission date 17/05/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 24/08/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/03/2018	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr E O'Broin

Contact details
Department of Plastic Surgery
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A prospective controlled trial comparing silicone and polyvinyl chloride (PVC) closed system wound drains

Study objectives
We hypothesise that wound drains made of silicone may be better tolerated by patients (because it is softer than PVC)

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Comfort associated with wound drains

Interventions
We will be comparing comfort levels between 2 different drains - silicone and polyvinyl chloride (PVC) closed system wound drains

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Discomfort assessed using an analogue pain scoring system

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2005

Completion date
01/09/2005

Eligibility

Key inclusion criteria
Patients undergoing plastic surgical procedures that require them to have at least 2 wound drains

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25-30

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2005

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Royal Infirmary
Department of Plastic Surgery
Infirmary Square

Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Leicester Royal Infirmary
Infirmary Square
Leicester
England
United Kingdom
LE1 5WW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
University Hospitals Leicester NHS 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