ISRCTN65306702 https://doi.org/10.1186/ISRCTN65306702

Femoral artery access wound study

Submission date 05/11/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 16/11/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 15/05/2015	**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
Dr Jan Swinnen

Contact details
c/o Department of Surgery
Westmead Hospital
Westmead
Sydney
Australia
2145

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Femoral artery access wound study

Study objectives
Open access to the femoral vessels is traditionally through a vertical incision. Although this approach gives good surgical access, wound healing can be complicated by sepsis, lymphatic leaks and wound breakdown.

Some causes for wound infections in vascular surgery are well known including emergency surgery, diabetes, having a groin incision and whether an autogenous or prosthetic graft is used. The effect of the type of groin incisions (vertical or transverse/oblique) on wound complications has been debated. There are a limited number of studies, which have looked at actual wound incision in terms of wound infection and lymphatic problems. These studies have been limited by either a short follow up or being a retrospective case analysis. These studies also did not assess the adequacy of the surgical access between the different incisions. We therefore conducted a prospective randomised study to look at the above problems.

Hypothesis:
The horizontal groin incision for femoral artery access has fewer wound complications than the vertical groin incision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Verbal ethics approval received from:
1. South Western Sydney Area Health Service Ethics Committee (Liverpool Hospital), February 2000, ref: 2000/022
2. Western Sydney Area Human Research Ethics Committee (Westmead Hospital), March 1999, ref: HREC2000/9/4.19(1090)

Formal ethics approval documents received from:
1. Westmead Hospital Ethics Committee (Australia), 12/09/2000
2. Liverpool Hospital Ethics Committee (Australia), 16/04/2000

This arrangement was due to the infrequent meetings of the ethics committees.

Study design
Randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Femoral artery access

Interventions
Treatment arms were:
1. Patients with a vertical femoral access incision, or
2. Patients with a horizontal femoral access incision
Duration of treatment was the operation duration. Total follow up was 28 days.

The surgical technique used for the transverse incision was as follows: an incision above the groin skin crease when the main vessel to be accessed was the common femoral artery whilst it was placed below the groin skin crease when the main vessels to be accessed were the profunda femoris or superficial femoral arteries. The deep dissection was the same as that used for vertical incisions.

Please note that recruitment for the two centres were as follows:
1. Westmead Hospital started recruiting in May 1999 following verbal approval from the Westmead Hospital Ethics Committee, and finished recruiting in December 2000
2. Liverpool Hospital started recruiting in February 2000 following verbal approval from the Liverpool Hospital Ethics Committee, and finished recruiting in December 2000

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Uncomplicated healing

Secondary outcome measures
1. Wound infection
2, Lymphatic leak
3. Wound dehiscence

Wounds were examined at 4 days, 10 days and 28 days.

Overall study start date
01/03/1999

Completion date
31/12/2000

Eligibility

Key inclusion criteria
1. Patients over the age of 18 and who could give informed consent
2. Consecutive patients undergoing vascular surgery involving femoral artery access

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 incisions

Key exclusion criteria
1. Redo vascular surgery to the femoral artery
2. Operating surgeon preference to withhold from trial

Date of first enrolment
01/05/1999

Date of final enrolment
31/12/2000

Locations

Countries of recruitment
Australia

Study participating centre
Westmead Hospital
Sydney
Australia
2145

Sponsor information

Organisation
Westmead Hospital (Australia) - Department of Surgery

Sponsor details
c/o Professor John Fletcher
Westmead
New South Wales

Australia
2145

Sponsor type
Hospital/treatment centre

Website
http://www.swahs.health.nsw.gov.au/westmead/index.htm

ROR
https://ror.org/04gp5yv64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Westmead Hospital and Liverpool Hospital (Australia) - Department of Surgery

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