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Does the use of sutures reduce the wound complication rate following surgery in hip fractures?

Submission date
13/05/2020

Recruitment status
No longer recruiting

Registration date
18/01/2021

Overall study status
Completed

Last Edited
18/01/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
The femoral neck is the most common location for a hip fracture. About 75,000 femoral neck are treated by the NHS every year. The reported incidence of wound complications is around 10%. Recent research has suggested an increased risk of infection. The aim of this study is to investigate wound healing and complications related to surgery following neck of femur fracture in the elderly. The aim is to compare wound problems and infection following two different methods of skin closure: subcuticular monocryl suture or metal clips.

Who can participate?
All patients admitted with intracapsular or extracapsular neck of femur fracture and undergoing either hemiarthroplasty or Dynamic Hip Screw operation and with mental capacity.

What does the study involve?
Participants are randomly allocated to be treated with either subcuticular monocryl suture or metal clips for skin closure after surgery. Wound problems, infection and duration of surgery are compared.

What are the possible benefits and risks of participating?
The possible benefits are that the wound healing process can be closely monitored associated with the standard wound closure methods used (sutures and metal clips). The researchers do not anticipate any risks as such.

Where is the study run from?
Medway Maritime Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2012 to January 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr Rajesh Bawale, rajesh.bawale@nhs.net
Prof. Bijayendra Singh, bijayendra.singh@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mr Rajesh Bawale

ORCID ID
https://orcid.org/0000-0002-3127-0105

Contact details
Medway Maritime hospital
Windmill road
Gillingham
Gillingham
United Kingdom
ME7 5NY
+44 (0)1634 830000
rajesh.bawale@nhs.net

Type(s)
Scientific

Contact name
Prof Bijayendra Singh

Contact details
Medway Maritime hospital
Windmill road
Gillingham
Gillingham
United Kingdom
ME7 5NY
+44 (0)1634 830000
bijayendra.singh@nhs.net

Additional identifiers

Study information

Scientific Title
Use of sutures reduces wound complication rate following surgery in hip fractures - a prospective randomised trial

Study objectives
Orthopaedic surgical site infections are one of the most important and often devastating post-operative complications and can prolong hospital stay by a few days to weeks. Hence choosing the appropriate method of wound closure to prevent wound complications is vital. There is no consensus in the literature as to which skin closure method is better. The aim of this study is to compare the wound problems and infection following two different methods of skin closure: subcuicular sutures and metal clips.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2012, NRES Committee London - Queen Square (Room 4W/12, 4th Floor West, Charing Cross Hospital, Fulham, Palace Road, London, W6 8RF, UK; +44 (0)20 3311 7287; queensquare.rec@hra.nhs.uk), REC ref: 11/LO/1452

Primary study design
Interventional

Study design
Prospective single-centre randomized parallel trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Recovery from surgery for fractured neck of femur

Interventions
The randomisation and the allocation are done by using sequentially numbered opaque and unmarked sealed envelopes.

After completion of the hip hemiarthroplasty and dynamic hip screw surgery, the surgical wounds are closed with either metal clips or the 3-0 absorbable poliglecaprone as allocated following randomisation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Wound problems measured using Singh’s Wound Score (SWS) at days 2, 5, 7, 10 and 14 days
2. Wound infection measured using Singh’s Wound Score (SWS) at days 7,10 and 14 days

Key secondary outcome(s)
Duration of surgery (min) measured using patient records at the end of surgery

Completion date
15/01/2018

Eligibility

Key inclusion criteria
1. Admitted with intracapsular or extracapsular neck of femur fracture
2. Undergoing either hemiarthroplasty or dyanmic hip screw operation
3. Mental capacity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
526

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
24/07/2012

Date of final enrolment
04/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medway Maritime Hospital
Windmill Road
Gillingham
Gillingham
United Kingdom
ME7 5NY

Sponsor information

Organisation
Medway Maritime Hospital

ROR
https://ror.org/02380m508

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. B Singh (bijayendra.singh@nhs.net) and Mr R Bawale (rajesh.bawale@nhs.net).

IPD sharing plan summary
Available on request