

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

<b>Submission date</b> 13/05/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/01/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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](mailto:rajesh.bawale@nhs.net)

Prof. Bijayendra Singh, [bijayendra.singh@nhs.net](mailto:bijayendra.singh@nhs.net)

## Contact information

### Type(s)

Scientific

### Contact name

Mr Rajesh Bawale

### ORCID ID

<http://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](mailto: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](mailto:bijayendra.singh@nhs.net)

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

**Secondary identifying numbers**

Nil known

## **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: subcuticular 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

**Study design**

Prospective single-centre randomized parallel trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel 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**

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 measure**

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

### **Secondary outcome measures**

Duration of surgery (min) measured using patient records at the end of surgery

### **Overall study start date**

05/04/2012

### **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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

500

### **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**

England

United Kingdom

**Study participating centre****Medway Maritime Hospital**

Windmill Road

Gillingham

Gillingham

United Kingdom

ME7 5NY

**Sponsor information****Organisation**

Medway Maritime Hospital

**Sponsor details**

c/o Dr Edyta McCallum

Windmill Road

Gillingham

England

United Kingdom

ME7 5NY

+44 (0)1634 830000 Extn 3030

edyta.mccallum@nhs.net

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/02380m508>

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

**Publication and dissemination plan**

1. Study protocol and statistical analysis plan are available on request
2. Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/02/2021

**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