ISRCTN40402832 https://doi.org/10.1186/ISRCTN40402832

Reduction Of Surgical Site Infection using a Novel Intervention

Submission date	Recruitment status
01/07/2009	No longer recruiting
Registration date	**Overall study status**
14/10/2009	Completed
Last Edited	**Condition category**
02/08/2013	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.rossini.bham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Reduction Of Surgical Site Infection using a Novel Intervention: a randomised controlled trial

Acronym
ROSSINI

Study objectives
The aim of the ROSSINI trial is to investigate whether the use of a wound-edge protection device in adult patients undergoing abdominal surgery experience a lower rate of surgical site infection (SSI) than those cases not utilising the device.

As of 15/03/2010 this record was updated to include a change the the anticipated start date of this trial; the initial anticipated start date was 01/09/2009.

As of 09/05/2012, the anticipated end date of this trial has been updated from 31/08/2014 to 31 /03/2012. Target number of participants for the trial has been updated from 750 to 769.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 15/03/2010: North Staffordshire Research Ethics Committee approved (ref: 09/H1204/91)

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
Wound infection

Interventions

The intervention is the use of a 'wound edge protector', a device which is placed in the wound during surgery and aims to reduce contamination of the wound edges and therefore reduce post-operative wound infection. The device is removed at the end of the procedure. Patients will be randomised to 2 arms - wound protector or no wound protector. Other aspects of their treatment/surgery will remain unchanged.

Follow up will consist of blinded wound review at day 5 - 7 (prior to discharge) and again in outpatients at around 30 days. A patient questionnaire covering the intervening time period will also be completed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Incidence of post-operative wound infection, assessed at 7 and 30 days

Secondary outcome measures
Assessed at 30 days:
1. Health related quality of life
2. Length of hospital stay
3. Cost effectiveness
4. The effect on the efficacy of a wound edge protection device in reducing wound infection of:
4.1. Degee of abdominal contamination
4.2. Comorbidity
4.3. Duration of surgery
4.4. Grade of surgeon closing the wound

Overall study start date
22/02/2010

Completion date
31/03/2012

Eligibility

Key inclusion criteria
All adults (greater than 18 years of age, either sex) undergoing laparotomy via a midline incision (for any surgical indication), including both elective and emergency operations.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
769 (Amended on 09/05/2012: Recruitment completed, in analysis phase)

Key exclusion criteria
1. Patients less than 18 years of age, or unable to give informed consent
2. Laparoscopic-assisted cases

Date of first enrolment
22/02/2010

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Birmingham,
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details
c/o Dr Christopher Counsell
Birmingham Clinical Research Office
HSRC Building
University of Birmingham
Birmingham
England
United Kingdom
B15 2TT

Sponsor type

Hospital/treatment centre

Website
http://www.uhb.nhs.uk

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) funding pending

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?
Protocol article	protocol	04/10/2011		Yes	No
Results article	results	31/07/2013		Yes	No