ISRCTN61444699 https://doi.org/10.1186/ISRCTN61444699

Recognition and expertise in the prevention of anal incontinence from ruptured sphincter

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2017	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0158108052

Study information

Scientific Title
The REPAIR study - Recognition and Expertise in the Prevention of Anal Incontinence from Ruptured Sphincter: a randomised controlled trial

Acronym
REPAIR

Study objectives
Which method of surgical repair for 3rd and 4th degree obstetric anal sphincter injury results in the better outcome (the overlap method or the juxtaposition method), in terms of the incidence of anal incontinence at 12 months postpartum?

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
Urological and Genital Diseases: Anal incontinence

Interventions
The proposed trial is a conventional randomised controlled trial of surgical method in the management of an infrequent complication of childbirth that nevertheless blights the lives of many thousands of women in the UK, and more worldwide. The team also hope to be able to

draw conclusions about the impact on outcome that arises from the individual skill of the clinician undertaking the repair.

Intervention Type
Procedure/Surgery

Primary outcome measure
Anal incontinence at 1 year after repair

Secondary outcome measures
Quality of life 1 year after repair

Overall study start date
01/10/2002

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. All women with complete obstetric anal sphincter rupture (3rd or 4th degree perineal tear)
2. Informed consent is given
3. Authorised clinician available to perform or supervise the repair

Participant type(s)
Patient

Age group
All

Sex
Female

Target number of participants
Not provided at time of registration (recruitment completed)

Key exclusion criteria
1. Previous surgery for obstetric repair or anal fistula
2. Refuse or withdraw consent

Date of first enrolment
01/10/2002

Date of final enrolment
31/12/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Charity

Funder Name
North Staffordshire Medical Institute

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