

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/07/2017	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Anal incontinence at 1 year after repair

Key secondary outcome(s)

Quality of life 1 year after repair

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

Healthy volunteers allowed

No

Age group

All

Sex

Female

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**

United Kingdom

England

Study participating centre

University of Birmingham

Birmingham

United Kingdom

B15 2TG

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Charity

Funder Name

North Staffordshire Medical Institute

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration