ISRCTN50105150 https://doi.org/10.1186/ISRCTN50105150

Sitz bath for acute anal pain: cold or warm?

Submission date 27/11/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/01/2009	**Overall study status** Completed	
Last Edited 29/06/2010	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr David Parés

Contact details
Hospital del Mar
Colorectal Surgery Unit
Passeig maritim 25 - 29
Barcelona
Spain
08003

Additional identifiers

Protocol serial number
001

Study information

Scientific Title
Sitz bath for acute anal pain: cold or warm? A randomised controlled trial

Acronym
FRI.CA study

Study objectives

A warm sitz bath is better than a cold one to relieve acute anal pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics board on the 2nd February 2006 (ref: 2005/2203/I)

Primary study design
Interventional

Study design
Randomised controlled, two-arm trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute anal pain from haemorrhoids or anal fissure

Interventions
Treatment with sitz bath every 12 hours during 7 days. Follow-up will be performed every day during the first 7 days of the study. Recommendations of temperature for sitz bath, diary record of temperature and pain (Visual Analogue Scale [VAS]) will be assessed.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Pain control, evaluated using the VAS during the first 7 days of the study.

Key secondary outcome(s)
Outcome of disease (haemorrhoids or fissure), measured during the first 7 days of the study.

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Adult patients aged over 18 years, either sex
2. Acute anal pain for haemorrhoids or anal fissure
3. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. No acceptance
2. Previous anal surgery

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Spain

Study participating centre
Hospital del Mar
Barcelona
Spain
08003

Sponsor information

Organisation
Hospital del Mar (Spain)

ROR
https://ror.org/03a8gac78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital del Mar (Spain)

Results and Publications

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?
Results article	results	01/08/2010		Yes	No