

# Sitz bath for acute anal pain: cold or warm?

<b>Submission date</b> 27/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/06/2010	<b>Condition category</b> Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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Barcelona  
Spain  
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## 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/l)

### **Study design**

Randomised controlled, two-arm trial

### **Primary study design**

Interventional

### **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?
<a href="#">Results article</a>	results	01/08/2010		Yes	No