

# Comparison of sclerotherapy for first-grade haemorrhoids using aethoxysklerol® foam versus fluid: a randomised, controlled, multicentre, single-blinded trial

<b>Submission date</b> 12/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/08/2021	<b>Condition category</b> Circulatory 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

### Contact name

Dr Karl-Heinz Moser

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

004

# Study information

## Scientific Title

Comparison of sclerotherapy for first-grade haemorrhoids using aethoxysklerol® foam versus fluid: a randomised, controlled, multicentre, single-blinded trial

## Acronym

Haemorrhoidal sclerotherapy

## Study objectives

To test whether the rate of persisting haemorrhoidal bleeding is different after a single session of infection sclerotherapy using Aethoxysklerol® 3% foam versus fluid.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval pending from the local ethics committee (Ethikkommission der Ärztekammer Nordrhein).

## Study design

Randomised-controlled observer-blinded trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Bleeding first-grade haemorrhoids

## Interventions

Sclerotherapy using either Aethoxysklerol® foam or fluid.

## Intervention Type

Drug

## Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

Aethoxysklerol® foam or fluid

**Primary outcome measure**

Percentage of patients reporting persistent haemorrhoidal bleeding after the first sclerotherapy session. Patients will score bleeding in a daily fashion using a calendar. Persistent bleeding is defined as two days with bleeding in the interval after day two following sclerotherapy, or as one day with bleeding within the last three days before the follow-up visit on day 14.

**Secondary outcome measures**

1. Number of courses of repeat sclerotherapy
2. Percentage of patients with bleeding after a second sclerotherapy
3. Size of haemorrhoids
4. Total volume of Aethoxysklerol® necessary for therapy
5. Pain during and after therapy
6. Pruritus ani
7. Feeling of perianal wetness
8. Patient satisfaction
9. Perianal interventions other than sclerotherapy
10. Incidence of adverse events

**Overall study start date**

01/01/2007

**Completion date**

30/09/2007

**Eligibility****Key inclusion criteria**

Bleeding from first-grade haemorrhoids

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

130

**Key exclusion criteria**

1. Age under 18 or over 75 years
2. Pregnancy or breast-feeding
3. Allergy to polidocanol or other drug components
4. Perianal thrombosis
5. Faecal incontinence

6. Perianal fistula
7. Proctitis
8. Periproctal abscess
9. Anal eczema
10. Previous sclerotherapy for haemorrhoids
11. General allergic predisposition
12. Asthma bronchiale
13. Perianal bleeding from other causes than haemorrhoids
14. Severe general comorbidity hindering follow-up
15. Hypercoagulability
16. Concomitant anticoagulatory medication
17. Hereditary thrombophilia
18. Hepatitis B or C
19. Human Immunodeficiency Virus (HIV) infection
20. Crohn's disease
21. Colitis ulcerosa
22. Diabetes mellitus type I or II
23. Known gastrointestinal cancer
24. General infection
25. Participation in another drug trial within the last 30 days
26. Legal or illegal drug dependency interfering with study compliance
27. Lack of German language proficiency
28. Lack of self-determination due to legal or authoritative adjudication
29. Psychoneurological disorders interfering with study compliance
30. Lack of compliance
31. Lack of written informed consent

**Date of first enrolment**

01/01/2007

**Date of final enrolment**

30/09/2007

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

Chirurgische Gemeinschaftspraxis Südstadt

Cologne

Germany

D 50678

## **Sponsor information**

## Organisation

Individual Sponsor (Germany)

## Sponsor details

Karl-Heinz Moser  
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D 50678

## Sponsor type

Other

## Funder(s)

### Funder type

Industry

### Funder Name

Chemische Fabrik Kreussler & Co. GmbH (Germany)

## 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?
<a href="#">Results article</a>		18/06/2013	20/08/2021	Yes	No