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

Submission date
12/12/2006

Registration date
05/03/2007

Last Edited
20/08/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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).

Primary study design
Interventional

Study design
Randomised-controlled observer-blinded trial

Study type(s)
Treatment

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(s)
Percentage of patients reporting persistant haemorrhoidal bleeding after the first sclerotherapy session. Patients will score bleeding in a daily fashion using a calendar. Persistant 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.

Key secondary outcome(s)

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

Completion date
30/09/2007

Eligibility

Key inclusion criteria
Bleeding from first-grade haemorrhoids

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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 authorative 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)

Funder(s)

Funder type
Industry

Funder Name

Chemische Fabrik Kreussler & Co. GmbH (Germany)

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		18/06/2013	20/08/2021	Yes	No