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Patient satisfaction in the treatment of anal fissure

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/08/2009	Digestive System	[ ] 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
NTR441; 2004/149

Study information

Scientific Title

Study objectives

Treatment of anal fissure with isosorbide dinitrate (ISDN) or Botulinum toxin A gives approximately comparative outcomes. Because of intensive treatment with isosorbide dinitrate cream, patients treated with Botulinum toxin A will be more satisfied. After six weeks treatment with Botulinum toxin A, the patient satisfaction will be significant more than patients treated with isosorbide dinitrate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Primary study design
Interventional

Study design
Multicentre randomised single blind active controlled parallel trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anal fissure

Interventions
ISDN 1% cream versus Botuline Toxine A for a duration of 12 weeks.
ISDN cream application every 4 hours for 12 weeks.
Botulinum Toxin A injection at week 0 and if necessary again at week 6.
Botulinum Toxin A Dysport® is made by Ipsen.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Botulinum toxin A (Dysport®), isosorbide dinitrate

Primary outcome(s)
1. Patient satisfaction after 6 weeks
2. Visual Analogue Score on weeks 0, 6 and 12

Key secondary outcome(s)
1. Patient satisfaction after 12 weeks
2. Pain after defecation at night
3. Incontinence after 6 and 12 weeks
4. Healing of fissure after 6 and 12 weeks

Completion date
01/07/2007

Eligibility

Key inclusion criteria
1. Diagnosed anal fissure with complaints
2. Complaints longer than 2 months
3. Age 21-60 years
4. Dutch speaking
5. Will-competent
6. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnancy, lactation
2. Muscle-sicknesses such as myasthenia gravis
3. Simultaneous use of medication interacting with neuromuscular transmission
4. Fistulas
5. Coagulation disorders or the use of anticoagulants
6. Anal surgery in the past
7. Haemorrhoids or inflammatory bowel sicknesses as a cause of anal fissure
8. Major secondary changes because of the anal fissure

Date of first enrolment
08/11/2004

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

Sint Lucas Andreas Ziekenhuis
Amsterdam
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1006 AE

Sponsor information

Organisation
Ipsen Farmaceutica B.V. (Netherlands)

ROR
https://ror.org/026jmga48

Funder(s)

Funder type
Industry

Funder Name
Ipsen Farmaceutica B.V. (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration