Patient satisfaction in the treatment of anal fissure.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27756

Source
NTR

Brief title
N/A

Sponsors and support

Primary sponsor: Ipsen Farmatherapeutica bv
Hoofdweg Oostzijde 620
2132 MJ Hoofddorp nederland
tel: 023-5541600
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www.IPSEN.NL@IPSEN.com
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Intervention

Outcome measures

Primary outcome

1. Patient satisfaction after 6 weeks;

2. Visual Analoge Score on week 0,6 and 12.

Secondary outcome

1. Patientsatisfaction after 12 weeks;

2. Pain after defecation en at night;

3. Incontinence after 6 and 12 weeks;

4. Healing of fissura after 6 and 12 weeks.

Study description

Background summary

Prospective randomised multicentre trial of satisfaction of treatment of anal fissure with isosorbide dinitrate or botuline toxin A injections.

Study objective

Treatment of anal fissura with isorsorbide dinitrate or Botuline toxine A gives approximately comparative outcomes. Because of intensive treatment with isosorbide dintrate creme, patient treated with Botuline toxine A wil be more satisfactioned. After six weeks treatment with Botuline toxine A, the patient satisfaction wil be significant more than patients treated with isosorbide dinitrate.

Study design

N/A

Intervention

ISDN1% Creme versus Botuline Toxine A
Duration 12 weeks.

ISDN creme application every 4 ours for 12 weeks.

Or Botuline Toxine A injection at week 0 and if neccesary at week 6 again
Botuline Toxine A Dysport fabrikant Ipsen.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosed anal fissura with complaints;

2. Complaints longer than 2 months;

3. Age 21-60 year;

4. Speaking dutch;

5. Will-competent;

6. Informed consent.

Exclusion criteria

1. Pregnancy, lactation;

2. Muscle-sicknesses such as myasthenia gravis;

3. Simultaneous use of medication interacting with neuromusculair transmission;

4. Fistulas;

5. Coagulation disorders or th use of anticoagulantia;

6. Anal surgery in the past;

7. Haemorrhoiden or inflammatory bowel sicknesses as a cause of anal fissure;

8. Major secundaire changes because of the anal fissure.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2004
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL402
NTR-old	NTR441
Other	: 2004/149
ISRCTN	ISRCTN85367943

Study results

Summary results
N/A