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The treatment of chronic anal fissures with fissure excision and Botulinum Toxin Type A injection

Submission date
29/07/2018

Recruitment status
No longer recruiting

Registration date
22/11/2018

Overall study status
Completed

Last Edited
16/11/2022

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Chronic anal fissure is a tear in the anal canal that lasts for more than 2 months and doesn't respond to non-surgical treatment. This can lead to severe pain during and after bowel movements. This condition is most frequent in younger and working-age adults.
A key symptom of this condition is internal sphincter spasms (spasms of the internal muscles in the anus) and this needs to be eliminated in order to make treatment effective. This can be done surgically and non-surgically; however, both methods have issues - non-surgical treatments often lead to relapse, and surgical treatment can lead to incontinence.
This study aims to improve the treatment of anal fissures by using a new method of eliminating sphincter spasms (injection with the Botulinum toxin) to reduce the number of patients suffering with incontinence after the treatment.

Who can participate?
Patients with chronic anal fissure

What does the study involve?
Patients are assigned to either the intervention or control groups. Participants in the intervention group are given an injection of Botulinum toxin type A to eliminate internal sphincter spasm. Participants in the control group are given pneumatic balloon dilation to eliminate internal sphincter spasm, which involves a small balloon being carefully opened inside the anus.
Pneumatic balloon dilatation of anal sphincter is performed in the control group. The diameter of the anal canal is initially measured during surgery. Then the balloon of the appropriate diameter
Participants will be tested for sphincter spasms, pain and incontinence before and after the surgery.

What are the possible benefits and risks of participating?
There are no known benefits to participants taking part in this study. The possible risk for participants in the intervention group is an allergic reaction to Botulinum toxin type A. The

possible risk to participants in the control group is that the dilation of the sphincter using the balloon could lead to temporary post-operative gas or incontinence.

Where is the study run from?
State Scientific Center of Coloproctology named after A.N. Ryzhykh of the Ministry of Healthcare of Russia

When is the study starting and how long is it expected to run for?
January 2017 to September 2019

Who is funding the study?
State Scientific Center of Coloproctology named after A.N. Ryzhykh of the Ministry of Health of Russia (Russia)

Who is the main contact?
Dr Zharkov
zee@gnck.ru

Contact information

Type(s)
Scientific

Contact name
Mr Eugene Zharkov

ORCID ID
http://orcid.org/0000-0003-3403-9731

Contact details
Russia, Moscow, Saliam Adil, 2
Moscow
Russian Federation
123423
89039689739
drzharkov@mail.ru

Type(s)
Scientific

Contact name
Mrs Asmat Burtseva

ORCID ID
http://orcid.org/0000-0001-6689-8640

Contact details
Russia, Moscow, Saliam Adil, 2
Moscow
Russian Federation
123423

89262837362
Burtseva_oa@gnck.ru

Type(s)
Scientific

Contact name
Dr Sergei Frolov

ORCID ID
http://orcid.org/0000-0002-4697-2839

Contact details
Russia, Moscow, Saliam Adil, 2
Moscow
Russian Federation
123423

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
58

Study information

Scientific Title
Open comparative randomized clinical study of the influence of Botulinum Toxin Type A injection vs. anal dilatation with inflatable balloon in patients after chronic anal fissure excision on the frequency and duration of following anal sphincter insufficiency.

Study objectives
There will be a reduction in the frequency and duration of anal sphincter insufficiency after Botulinum Toxin Type A injection in comparison with pneumatic balloon dilatation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
State Scientific Center of Coloproctology named after A.N. Ryzhykh of the Ministry of Health of Russia. 10/02/2018, reference number: 58

Study design
Interventional prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chronic anal fissure

Interventions
Participants were randomised using the envelope method into either the intervention or control group. Before surgery, all participants will have their pain, anal incontinence and anorectal manometry assessed.
Participants in the intervention group underwent surgical removal of the anal fissure followed by internal sphincter relaxation with the Botulinum toxin type A. Sparing surgical removal of fissure without internal sphincter incision was completed under spinal anaesthesia in surgical room at lithotomy position using electrocoagulation. After that Botulinum toxin type A was injected into the internal anal sphincter at 3 and 9 o'clock, 5 U at each point (10 U in total).
Participants in the control group underwent surgical removal of the anal fissure with pneumatic balloon dilation to relax the sphincter. Under spinal anaesthesia at lithotomy position the appropriate graduated cone was inserted in anus by rotating motions under pressure not exceeding 2 kg until the maximum contact with anal canal walls. Each cone graduation corresponded to the certain diameter of the anal canal. Thereafter, the measuring device was removed and replaced with pneumatic balloon of the appropriate diameter covered with latex and lubricated with liquid paraffin. The balloon was gradually opening under air pressure (for 1 minute) up to 0.7 bar until reaching its maximum diameter and pneumatic balloon dilatation of anal sphincter was performed for 7 minutes. Thereafter, the balloon was deflated and removed from the anus. After that the anal canal and then surgical site were treated with aqueous chlorhexidine solution. Then, sparing surgical removal of anal fissure without internal anal sphincter incision was performed using electrocoagulation via a rectal speculum.
7 days following the surgery, anorectal manometry will be performed. Anal sphincter dysfunction will be assessed 30 days after surgery. At day 60, anodermal defect healing will be assessed, along with pain, anal incontinence and anorectal manometry.

Intervention Type
Procedure/Surgery

Primary outcome measure
Frequency of anal sphincter insufficiency, assessed using the Wexner score 60 days after surgery.

Secondary outcome measures

1. Frequency and structure of complications, assessed through clinical examinations at 7, 30 and 60 days after surgery
2. Pain syndrome assessed using visual analogue scale (VAS) before surgery and everyday until 60 days after surgery
3. Anorectal manometry parameters, assessed before surgery and 7 and 60 days after surgery, including:
3.1. Mean resting anal pressure
3.2. Maximum resting anal pressure
3.3. Mean squeezing anal pressure
3.4. Maximum squeezing anal pressure
4. Duration of temporary disability:
4.1. First day that patients return to work after surgery
4.2. 36-item Short Form Health Survey (SF-36) assessed the day after surgery, along with 30 and 60 days after
5. Frequency of post-operative wound epithelialization, assessed through a clinical examination of whether the wound has healed 60 days after surgery
6. Relapse rate, determined by the number of patients that return to the clinic with complaints of pain during the study period

Overall study start date
09/01/2017

Completion date
02/09/2019

Eligibility

Key inclusion criteria
1. Aged 18-70 years old
2. Chronic anal fissure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
70

Total final enrolment
52

Key exclusion criteria
1. Inflammatory disease of the colon
2. Pectenosis
3. Previous surgical interventions of the anal canal
4. II-IV grade internal haemorrhoids
5. Rectal fistula
6. Severe somatic diseases at the decompensation stage
7. Pregnancy
8. Lactation
9. Intolerance or hypersensitivity to Botulinum toxin
10. Myasthenia gravis and myasthenia-like syndromes

Date of first enrolment
17/10/2017

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
Russian Federation

Study participating centre
State Scientific Center of Coloproctology named after A.N. Ryzhykh
Saliam Adil 2
Moscow
Russian Federation
123423

Sponsor information

Organisation
State Scientific Centre of Coloproctology

Sponsor details
Russia, Moscow, Saliam Adil, 2
Moscow
Russian Federation
123423
84991991567
info@gnck.ru

Sponsor type
Hospital/treatment centre

Website
http://www.gnck.ru

ROR
https://ror.org/00c5s4m23

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
State Scientific Centre of Coloproctology

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
02/09/2020

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Evgeny Zharkov (info@gnck.ru) as an MS Access 2013 or Tibco Statistica 13 file. Data will become available after the end of the study for 3 years and will be shared with interested in scientists and publishers, for scientific analyses, after an official request by e-mail. The consent from participants is not necessary because according Russian federal law all data will be anonymised. When using data for re-analysis, reference to the source is required.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/03/2020	01/04/2020	Yes	No
Protocol file			16/11/2022	No	No