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Penis enlargement surgery, a report of 355 cases

Submission date	Recruitment status	[_] Prospectively registered
23/03/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2023	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Many men worry that their penis is too small and some want them to be increased in size. Penile enhancement surgery is a type of medical procedure which involves increasing the length or girth of the penis. Penis enlargement surgery can have complications, and many men are unhappy with the results. The aim of this study is to look at men who have penis enlargement surgery as part of their normal care to look at how well the procedure works.

Who can participate?
Healthy men who are undergoing penis enlargement surgery.

What does the study involve?
Participants undergo surgery to increase the length or girth of their penises as part of normal care. Routine information is collected about each patient's background, health and the size of their penis at the start of the study and then two, six and twelve months after they have their surgery. The researchers collect this information by reviewing medical records in order to see how effective the surgery has been.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Blumar Medica (Italy)

When is the study starting and how long is it expected to run for?
October 2012 to December 2015

Who is funding the study?
Investigator initiated and funded (Italy)

Who is the main contact?
1. Dr Alessandro Littara (public)
2. Dr Claudia Schmid (scientific)

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Penile lengthening and girth enhancement surgery, a report of 355 cases

Study objectives
The aim of this study is to report and evaluate the results and complications of penile enhancement surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study does not require ethics approval.

Study design
Retrospective cohort analysis

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Penile hypoplasia and/or normal penile size

Interventions
Study participants are regular patients that receive penile enhancement in normal care, i.e. no special procedures, devices or treatments are added or carried out for the purpose of the study.

Routine information is collected for each patient, including age, weight, height, marital status, type of procedure (penile lengthening, girth enhancement, or both), IIEF (International Index of Erectile Function) score, baseline penile length at rest, stretched length (as a proxy for erect length), penile girth at rest. The same measurements are repeated at 2, 6 and 12 month follow-up visits. IIEF is repeated at 12 months.

This data is then collected through retrospective chart review by the researcher.

Intervention Type
Procedure/Surgery

Primary outcome measure
Penile length and/or girth, as measured in centimeters at baseline, patient discharge and 2, 6 and 12 months, is collected through patient chart review.

Secondary outcome measures
Erectile function, as measured using the the IIEF test at baseline and 12 months, is collected through patient chart review.

Overall study start date
25/10/2012

Completion date
22/12/2015

Eligibility

Key inclusion criteria
1. Male
2. Aged between 18 and 64 years old
3. In good health
4. No micropenis
5. Realistic expectations
6. Absence of psychiatric or systemic disorders

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
355

Total final enrolment
355

Key exclusion criteria
1. Men with unrealistic expectations
2. Psychiatric disorders
3. Systemic disorders
4. Bleeding disorders
5. Heart disease

Date of first enrolment
10/01/2013

Date of final enrolment
07/12/2015

Locations

Countries of recruitment
Italy

Study participating centre
Blumar Medica
Viale Vittorio Veneto 14
Milan
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Sponsor information

Organisation
Dr. Alessandro Littara

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/04/2019	06/06/2023	Yes	No