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Neomercurocromo and colloidal silver for penile lichen sclerosus

Submission date
04/06/2017

Recruitment status
No longer recruiting

Registration date
23/06/2017

Overall study status
Completed

Last Edited
19/01/2018

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Lichen sclerosus is a long-term skin condition which causes itching and white patches to appear on the skin. The condition most commonly affects the genitalia. The exact cause is unclear however it is thought to be related to over activity of the immune system (the body's natural defences). Neomercurocromo is a cream used to treat certain skin conditions. Colloidal silver is a mineral which is used as a homeopathic treatment for a range of conditions. The aim of this study is to find out whether treatment with a combination of Neomercurocromo and colloidal silver is effective for treating lichen sclerosus.

Who can participate?
Men with lichen sclerosus present on their genitalia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given Neo-Mercurocromo to rub on the affected areas twice a day for two weeks, followed by colloidal silver to apply twice a day for a further two weeks. Those in the second group are given a salt water solution to rub on the affected area twice a day for four weeks. At the start of the study and after one and three months, participants have their lichen sclerosus assessed as well as completing a questionnaire about their quality of life.

What are the possible benefits and risks of participating?
Participants who receive the treatment may benefit from an improvement to their condition or cure. There are no notable risks involved with participating.

Where is the study run from?
Gynepro Medical (Italy)

When is study starting and how long is it expected to run for?
March 2017 to December 2018

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

Who is the main contact?
1. Dr Carlo Maretti (scientific)
2. Dr Giorgio Cavallini (public)

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017/1

Study information

Scientific Title

Topical application of Neomercurocromo and subsequently of Colloidal Silver (active drugs) or of placebo (NaCl 0.9%) for the treatment of lichen sclerosus: Comparison of efficacy and of safety

Acronym
ELST

Study objectives
The aim of this study is to evaluate the efficacy of the topical treatment of penile lichen sclerosus with Neomercurocromo and later with colloidal silver.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gynepro Ethics Board, 10/05/2017, ref: CdB 01/2017

Study design
Randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use te contact details below to request a participant information sheet.

Health condition(s) or problem(s) studied
Lichen sclerosus of male genitalia

Interventions
Patients will be randomly assigned to one of the two groups using an online randomizer: https://www.randomizer.org/

Intervention group: Participants receive active drugs (Neo-Mercurocromo and Colloidal Silver). They are instructed to carefully rub a sterile gauze soaked with Neo-Mercurocromo against affected area(s) twice a day for two weeks. The composition of Neo-Mercurocromo is: Eosin 2%, Cloroxilenol 0,3%, Propilenglicol 30%. Following this, patients are instructed to carefully rub a sterile gauze soaked with Colloidal Silver (Argento Colloidale Puro, Hydromed, Schio (Vicenza-Italy)), twice a day for two weeks.

Control group: Sterile physiological solution (NaCl 0.9%) is used as control substance. The patients are instructed to carefully rub the affected area(s) twice a day for four weeks with a sterile gauze soaked with sterile NaCl 0.9%.

Participants in both groups are follow up after one and three months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Neomercurocromo, Colloidal silver.

Primary outcome measure
Lichen Sclerosus (LS) is measured using the LS specific scale at baseline, 1 and 3 months.

Secondary outcome measures
1. Quality of life is measured using the Dermatology Life Quality Index (DLQI)2 at baseline, 1 and 3 months
2. Patient impression of improvement is measured using the Patient Global Impression of Improvement (PGI-I) scale at baseline, 1 and 3 months

Overall study start date
23/03/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Male
2. Aged 18-70 years
3. Referred with a history of lichen sclerosus (LS) of genitalia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex

Male

Target number of participants
Minimum of 40 patients in each study arm

Key exclusion criteria
1. HIV infection
2. Any previous treatment for lichen
3. Any other present or past dermatologic disease of male genitalia
4. Penile or scrotal surgery or peircings

Date of first enrolment
16/05/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
Italy

Study participating centre
Gynepro Medical
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Sponsor information

Organisation
Gynepro Medical

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03segdh23

Funder(s)

Funder type
Other

Funder Name
Investigators initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Short communications to national and international congressess have been planned as well.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Giorgio Cavallini MD (giorgiocavallini@libero.it)

IPD sharing plan summary
Available on request