

Neomercurocromo and colloidal silver for penile lichen sclerosis

Submission date 04/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/01/2018	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims:

Lichen sclerosis 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 sclerosis.

Who can participate?

Men with lichen sclerosis 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 sclerosis 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

Contact name

Dr Carlo Maretti

Contact details

Gynepro Medical
via Tranquillo Cremona 8
Bologna
Italy
40137

Type(s)

Public

Contact name

Dr Giorgio Cavallini

ORCID ID

<http://orcid.org/0000-0002-1673-3482>

Contact details

Gynepro Medical
via Tranquillo Cremona 8
Bologna
Italy
40137

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 the 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

via tranquillo cremona 8

Bologna

Italy

40137

Sponsor information

Organisation

Gynepro Medical

Sponsor details

via Tranquillo Cremona 8

Bologna

Italy

40137

+39 051 442094

info@ginepro.it

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 congresses 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