The use of antibiotics in therapy resistant Lichen Sclerosus patientes

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To examine whether the use of systemically administered antibiotics in therapy resistant Lichen Sclerosus leads to:- Relief of symptoms- Improvement of clinical picture- Improvement of histological abnormalities- Effect on quality of life-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON33045

Source
ToetsingOnline

Brief title
Antibiotics in Lichen Sclerosus

Condition

- Bacterial infectious disorders
- Cornification and dystrophic skin disorders

Synonym
Lichen Sclerosus (geen lekenterm bekend)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Antibiotics, Lichen Sclerosus, Therapy resistant

Outcome measures

Primary outcome

- Relief of symptoms

Secondary outcome

- Improvement of clinical picture

- Improvement of histological abnormalities

- Effect on quality of life

- Demonstration of Borrelia species in the biopsies via culture and PCR

- Demonstration of antibodies to Borrelia species in serum of patients

- Feasibility for the patient (side effects, compliance with therapy regimen)

Study description

Background summary

Lichen Sclerosus (LS) is a chronic disorder of the skin and is considered a premalignant condition. The cause of LS is unknown, several causative factors have been suggested, under which an infection with Borrelia Burgdorferi. The treatment with the best evidence of efficacy is topical ultrapotent corticosteroid ointment. The majority of the patients responds well to this therapy regimen, however there is a small subgroup of patients that does not or hardly respond. In these patients, LS leads to complaints of itch and pain, with a great impact on the quality of life. For these patients limited options exist to treat the LS.

Study objective

To examine whether the use of systemically administered antibiotics in therapy resistant Lichen Sclerosus leads to:
- Relief of symptoms
- Improvement of clinical picture

- Improvement of histological abnormalities
- Effect on quality of life
- Demonstration of Borrelia species in the biopsies
- Demonstration of Borrelia in serum of patients
- A feasible therapeutic option for the patient (side effects, compliance with therapy regimen)

Study design

Ten patients with histologically proven LS, who do not or hardly respond to the standard therapy regimen will be asked to participate in the study.
Before the prescription of Penicillin G Benzathine, two biopsies will be taken en patients will be asked to fill in a questionaire, indicate a score for their itch (from 0 - 10). A digital photograph is made to be able to compare with the picture after therapy.
After two doses (4 weeks) the side effects will be evaluated, the itch score will be asked and a digital photograph taken.
After three months: itch score, a digital photograph, a biopsy when the LS has already significantly improved and a questionnaire.
After six months: itch score, a digital photograph, a biopsy when this was not already done at three montns and a questionnaire. When the Penicillin G Benzathine is effective, the patient is advised to continue the use of it.

Intervention

Amoxicillin tablets 500 mg for 30 days followed by a maintenance therapy with Pencillin G benzathine 2.4 million units intramuscular, every two weeks for the six-twelve weeks.
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Study burden and risks

The burden and risks for the patients are small; the burden consists of four visitis to the outpatients clinic within 6 months, two biopsies and one venapunction. During the study 6 doses of Penicillin G Benzathine are presribed, to be administrated intramuscular.
The risks of the procedures are bleeding and infection after the biopsies. An allergic reaction to Penicillin or side effects. The change of an allergic reaction is small, side effects are more common but usually are mild.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Vulvar Lichen Sclerosus patients who do not or hardly respons to the standard therapy (ultrapotent corticosteroids)

Exclusion criteria

History of differentiated vulvar intraepithelial neoplasia or vulvar squamous cell carcinoma

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Amoxicillin
Generic name:	Amoxicillin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Benzathinebenzylpenicillin
Generic name:	Penidural
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	22-06-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	26-08-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2009-011906-40-NL
CCMO	NL27659.091.09