A prospective *proof of concept study* to evaluate the potential efficacy of ustekinumab in patients with moderate to severe hidradenitis suppurativa (acne ectopica)

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Primary objective: 1. To evaluate the effect of ustekinumab in patients with moderate to severe hidradenitis suppurativa (Hurley II-III), measured by disease specific score systmes: Sartorius/HS-LASI and PGA 2. To evaluate possible changes in scores…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin appendage conditions
Study type	Interventional

Summary

ID

NL-OMON37989

Source
ToetsingOnline

Brief title
HiTS (Hidradenitis suppurativa Treatment with Stelara)

Condition

- Skin appendage conditions

Synonym
hidradenitis suppurativa; acne ectopica; acne inversa

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Janssen-Cilag,Janssen-Cilag International NV

Intervention

Keyword: acne ectopica, efficay of ustekinumab, hidradenitis suppurativa, proof of concept

Outcome measures

Primary outcome

Primary study parameters:

• Number of patients with a clinical response to ustekinimab using the Sartorius/HS-LASI score. Clinical response is defined as >50% improvement at week 40.

• Number of patients with a clinical response to ustekinimab using the PGA. Clinical response is defined as a score of 0 (no disease activity) or 1 (mild disease activity).

• Number of patients with improved quality of life using the DLQI questionnaire and improvement in pain score using the VAS. A meaningfull improvement is defined as an improvement of the DLQI with at least 5 points and at least 50% improvement on the VAS.

Secondary outcome

• The correlation between serum Interleukine 2 Receptor (sIL2R) and HS disease activity measured by means of the Sartorius/HS-LASI score, PGA and CRP.

• The mean reduction in the serum inflammation parameter (CRP).

• The mean improvement of Skindex-29.

• Description of the histopathological characteristics of HS and the

histopathological differences before and after treatment by means of skin

biopsies. To evaluate if we can find an explanation for the cause of HS at RNA

levels.

• The percentual difference in clinical response between patients who have been

treated before with biologics (TNF-α non-responders) and patients who have

never been treated with biologics (bio-naive patients).

Study description

Background summary

Hidradenitis suppurativa, also known as acne inversa, is a chronic, often debilitating disease primarily affecting the axillae, perineum, and inframammary regions. Clinically, the disease often presents with tender subcutaneous nodules beginning around puberty. The nodules may spontaneously rupture or coalesce, forming painful, deep dermal abscesses. Eventually, fibrosis and the formation of extensive sinus tracts may result. The location of the lesions may lead to social embarrassment and the failure to seek medical treatment. Therapies in the past have consisted of long-term antibiotics, anti-androgens, and surgery. New treatments like tumor necrosis factor alfa (TNF-α) inhibitors have given clinicians more options against this difficult disease.

Study objective

Primary objective:
1. To evaluate the effect of ustekinumab in patients with moderate to severe hidradenitis suppurativa (Hurley II-III), measured by disease specific score systmes: Sartorius/HS-LASI and PGA
2. To evaluate possible changes in scores of patient reported outcome quationnaires (DLQI, VAS)

Secondary objectives:
1. measurement of infectionparameters in the blood (CRP, WBC, neutrophils in the blood)
2. To evaluate whether serum solubleIL2R (IL2R)is correlated to hidradenitis disease activity
- to evaluate a possible association between baseline sIL2R levels and the Hurley stage

-tot evaluate a possible association between sIL2R levels and the clinical aspect of HS during treatment with ustekunimab
3. To describe the histopathological characteristics of patients with HS and the possible changes in the histopathology after treatment with ustekinumab to evaluate whether on RNA level there is an explanation for the development of HS.
4. To describe the improvement in quality of life using the Skindex-29 questionnaire.
5.To evaluate if there is a difference in efficacy of ustekinumab in patients already treated with biologics (TNF-α non-responders) and patients never treated with a biologic .
6. To evaluate inflammation parameters on gene-expression level in the blood.

Study design

this is a prospective 'proof of concept' study with one treatment arm.

Intervention

patients < 100 kg receive a 45 mg subcutaneous injection with ustekinumab and patients > 100 kg a 90 mg subcutaneous injection with ustekinumab on week 0-4-16 and 28

Study burden and risks

On week 0-6-12-18-24-30-36-40 a total of 3 tubes of blood per visit are taken (1 of 4 1/2 cc, 2 of 4 cc) to monitor effect and side effect(s) of ustekinumab.
Furthermore we perform biopsies on week 0, 16 and 28 of lesional and healthy skin for histopathologic and immunohistochemical research, to monitor (possible differences in) effect before and after treatment.
On week 0-4-10-16-22-28-34-40-52 and 76 patients are asked to fill in questionnaires to measure quality of life before and after ustekinumab treatment. This will take 15-20 minutes at a time.
Risks associated with participation consist of side effects as described in the patientinformationfolder pages 4-6.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient above 18 to 65 years old
Patient with hidradenitis suppurativa Hurley stage II-III
Failure on conventional therapy with topical and oral antibiotics or immunosuppresiva or surgical intervention or on previous TNF alpha therapy (is not obligatory)
Patient has to be able to fill in a dutch formulated questionnaire
Signed informed consent
Women of childbaring age should use contraception

Exclusion criteria

Patients unable to fill in the questionnaires (mentally or physically)
Pregnancy or breast feeding patients
Patients with an active (chronic) infection, e.g. hepatitis B or C, HIV, tuberculosis
History of malignancy in past 10 years, except a basal cell carcinoma
Patients with demyelinating disease
Heartfailure NYHA class III-IV
Patients with a known allergy/hypersensitivity reaction to ustekinumab or one of the preservatives
Vaccination with living virus/bacterium < 3 months before starting ustekinumab

Severe liver or kidney dysfunction > 1.5 times of the maximum allowable value

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2012
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Stelara
Generic name:	ustekinumab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	26-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-02-2012
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-06-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-11-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2011-002091-16-NL
CCMO	NL36169.042.11