A partly blinded single center trial studying the effect of daily oral treatment with 30 mg prednisolone during two weeks on metabolic and disease activity parameters in patients with severe chronic atopic dermatitis and in healthy volunteers

Published: 16-07-2008
Last updated: 11-05-2024

Primary objectives:• To explore whether daily oral treatment with 30 mg prednisolone modulates biomarkers for adverse metabolic effects in a similar manner in patients with chronic atopic dermatitis as compared to healthy volunteers.• To determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON33879

Source
ToetsingOnline

Brief title
Prednisolone in atopic dermatitis an exploratory biomarker trial

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym

atopic dermatitis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Schering-Plough (voorheen Organon)
Source(s) of monetary or material Support: Farmaceutisch bedrijf: Organon;part of Schering-Plough

Intervention

Keyword: Atopic dermatitis, Biomarkers, Healthy volunteers, Prednisolone

Outcome measures

Primary outcome

The effect of prednisolone on several metabolic parameters will be measured in blood. Also will be studied whether the negative metabolic effects in AD patients are modulated in the same way as in healthy subjects. In group A and B disease activity will be assessed by a trained dermatologist.

Secondary outcome

Identification of biomarkers in blood (e.g. lymphocyte count) that reflect the immunosuppressive/ anti-inflammatory effect of daily oral treatment with 30 mg prednisolone in patients with chronic atopic dermatitis.

Study description

Background summary

Glucocorticoids (GCs) such as prednisolone are potent anti-inflammatory drugs that are crucial in the treatment of many autoimmune disorders including skin disorders like psoriasis and atopic dermatitis. Chronic use of high oral dosages of GCs is hampered by severe adverse effects that include metabolic changes. This can lead to a.o. induction of insulin-resistance which is strongly associated with elevated risk for cardiovascular disease and type 2

Diabetes. A main effort within pharmaceutical industry is the development of GCs with an increased therapeutic index; so called dissociating GCs (diss GC), with a better therapeutic index, as effective as prednisolone but shows less adverse reactions.
Of all indications that are treated with prednisolone, atopic dermatitis (AD) was selected as the most ideal indication for a trial examining prednisolone as these patients sometimes are treated with relatively high doses of oral prednisolone for a limited period of time with good effect on disease activity.

Study objective

Primary objectives:
• To explore whether daily oral treatment with 30 mg prednisolone modulates biomarkers for adverse metabolic effects in a similar manner in patients with chronic atopic dermatitis as compared to healthy volunteers.
• To determine the most suitable scoring method for quantification of the clinical effect of daily oral treatment with 30 mg prednisolone in patients with chronic atopic dermatitis.

Secondary objectives:
• To identify biomarkers that reflect negative effects and immunosuppressive / anti-inflammatory effects of daily oral treatment with 30 mg prednisolone in patients with chronic atopic dermatitis.

Study design

The subjects in this trial will be divided into three treatment groups:
Group A: Twelve subjects with chronic atopic dermatitis will be treated once daily during 15 days with 30 mg prednisolone in an open trial.
Group B: Twelve subjects with chronic atopic dermatitis will be randomized to one of the following treatments: B1) placebo on Day 0-1 and 30 mg prednisolone on Day 2-15 or B2) placebo on Day 0 and 30 mg prednisolone Day 1-15.
Group C: Twelve healthy volunteers will be randomized to one of the following treatments: C1) placebo on Day 0-1 and 30 mg prednisolone on Day 2-15 or C2) placebo on Day 0 and 30 mg prednisolone Day 1-15.

Intervention

Daily oral treatment with 30 mg prednisolone for 15 days. In group B and C placebo can be given instead of prednisolone for a maximum of 2 days.

Study burden and risks

Prednisolone treatment (30 mg daily during 2 weeks) is a normal treatment regime in daily practice. It is unlikely that is this period clinical significant negative effects will occur. Normal individuals treated with 30 mg

prednisolone will show a daily decrease of lymphocytes after the administration of the prednisolone. The decrease normalizes within 24 hrs after the administration. A 2-week treatment with a maximum of 30 mg prednisolone per day does not increase the infection risk. Lymphocyte numbers will however be frequently monitored during the trial.

Information about the possible negative effects associated with prednisolone use can be found in the information leaflet for the subjects and the product characteristics sheet (SmPC) provided by the supplier. Subjects with a clinically relevant medical history or current medical condition mentioned as contraindication or special warning in case of simultaneous prednisolone use, as mentioned in the protocol, are excluded from participation.
The total amount of blood drawn during the study will not exceed 500 ml.

Contacts

Public
Schering-Plough (voorheen Organon)

PO Box 20
5340 BH Oss
Nederland
Scientific
Schering-Plough (voorheen Organon)

PO Box 20
5340 BH Oss
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

For Patients with atopic dermatitis:
1. Atopic dermatitis according to the criteria of Hanifin and Rajka (1980).
2. Having severe chronic atopic dermatitis according to the treating dermatologist, in need of oral immunosuppressant treatment.;For all subjects:
3. Male or female at the age of 18-65 years (extremes included) on the day of the first dosing. Females of child bearing potential willing to use a double barrier method of birth control (e.g. hormonal contraception or IUD in combination with a condom or a diaphragm with spermicide) unless the subject has a vasectomized partner (> 6 months) or the subject is abstinent, during the trial.
4. Have a body weight resulting in a body mass index (BMI) of 20-32 kg/m2 (extremes included).

Exclusion criteria

For Patients with atopic dermatitis:
1. Having bacterial or viral infected eczema. ;For all subjects:
2. History of familiar Diabetes type II (first line).
3. Clinically relevant history or presence of any medical disorder, potentially interfering with the trial e.g., diabetes, presence of a clinically significant infection requiring continued therapy, severe diarrhea, active peptic ulcer disease and/or conditions needing special attention as mentioned in the Summary of Product Characteristics (SmPC) of prednisolone.
4. History of malignancy within the last five years.
5. Clinically relevant vital signs or physical findings at screening as judged by the investigator.
6. Fasting glucose level of >= 5.6 mmol/l.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2009
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	prednisolone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-10-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-12-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-02-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-07-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	28-07-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2007-001932-30-NL
CCMO	NL20045.041.08