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Clinical study to assess the efficacy and safety of Dalumin in patients with somatoform disorders

Submission date
22/05/2014

Recruitment status
No longer recruiting

Registration date
10/06/2014

Overall study status
Completed

Last Edited
12/06/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dalumin is an extract of a plant herb called Filipendula ulmaria. In studies with healthy people Dalumin was safe in doses up to 2400 mg. The aim of the study is to find out how effective Dalumin is at treating patients with somatoform disorders, a disease with physical symptoms that cannot be explained by a medical condition.

Who can participate?
Adult men and women with somatoform disorders

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives Dalumin for 10 weeks. The other group takes a placebo (dummy) instead. The severity of the symptoms of the disease are measured after 1, 2, 4, 7 and 10 weeks of treatment.

What are the possible benefits and risks of participating?
Participants who receive Dalumin could experience an improvement of their somatoform symptoms. There is no evidence available from the current information about any risks involved.

Where is the study run from?
About 40 selected centres (medical practices) in Germany

When is the study starting and how long is it expected to run for?
June 2014 to June 2016

Who is funding the study?
Dr Willmar Schwabe GmbH & Co. KG (Germany)

Who is the main contact?
Dr Stephan Klement
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Contact information

Type(s)
Scientific

Contact name
Prof Hans-Peter Volz

Contact details
Balthasar-Neumann-Platz 1
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
561501.01.004

Study information

Scientific Title
Multi-center, double-blind, placebo-controlled, randomized phase II study to assess the efficacy, safety and tolerability of Dalumin (WS® 1090) in patients with somatoform disorders

Study objectives
The objective of the study is to assess the efficacy of Dalumin in the treatment of patients with somatization disorder in comparing the change of the Hamilton Anxiety Scale total subscore somatic anxiety or the change of Somatic Symptom Inventory subset pain between baseline and Week 10 between Dalumin and placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the Medical Faculty of the University of Würzburg (Ethikkommission bei der Medizinischen Fakultät der Universität Würzburg), 08/05/2014, ref. 58/14_ff

Study design
Multi-centre randomized placebo-controlled double-blind phase II study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Somatization disorder (ICD 10, F45.0); Undifferentiated somatoform disorder (ICD 10, F45.1); Pain disorder (ICD 10, F45.4)

Interventions
The patients take two tablets (daily dose: placebo or Dalumin 600 mg or Dalumin 1200 mg) in the morning orally for 70 days. Randomization is carried out by a member of the sponsor who is not directly involved in the study conduct. The investigators receive numbered study medication in blocks of six. If a patient is to be randomised, he/she receives the drugs with the lowest available drug number.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Dalumin

Primary outcome measure
1. The individual difference of the total score of the Hamilton Rating Scale for Anxiety, somatic subscore (HAMAsom) between baseline and end of treatment (Week 10 or end of treatment in case of premature study termination)
2. Individual difference of the total score of the Somatic Symptom Inventory subset pain (SSIsp) between baseline and end of treatment (Week 10 or end of treatment in case of premature study termination) comparing Dalumin and placebo

Secondary outcome measures
1. Response criteria based on the HAMAsom total and on the SSIsp total score
2. Difference of the total score of the Montgomery-Asberg Depression Rating Scale (MADRS) between baseline and end of treatment. Response criteria based on the MADRS total score
3. Individual difference of single items of the HAMAsom, single items of the MADRS, total score and single items of the SSIsp; total score and subscales of the Sheehan Disability
4. Clinical Global Impressions of severity of disorder (CGI - item 1): Clinical Global Impressions of change from baseline (CGI - item 2)
5. Visual Analogue Scale overall pain (VASop)

6. Symptom Checklist 90 (SCL 90)
7. Frequency of patients who discontinue the study prematurely due to inefficacy
8. Adverse events, Laboratory data, ECG, vital signs

Overall study start date
30/06/2014

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Diagnosis of somatisation disorder
2. Undifferentiated somatoform disorder or pain disorder
3. Aged over 18 years
4. Severity of disorder: HAMAsom score ≥ 12, SSIsp 3 of 5 items ≥ moderate
5. BMI between 18 and 29.9 kg/m2
6. Written informed consent
7. Use of two different forms of highly effective contraception by females with childbearing potential

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
450

Key exclusion criteria
1. Any axis I disorder other than study indication within 6 months before the study
2. Risk of suicide or previous suicide attempt or clear display of autoaggressive behavior
3. History or evidence of alcohol and/or substance abuse or dependence
4. Current use of other psychotropic drugs within fivefold half-life of the drug before the baseline visit
5. History of hypersensitivity to Filipendula ulmaria or salicylates
6. Any unstable acute medical disorder
7. Unacceptability to discontinue or likelihood to need medication during the study that is prohibited as concomitant treatment
8. Non-medical psychiatric treatment during the course of the study
9. Clinical significant abnormality of ECG and/or laboratory value(s)
10. Pregnancy or lactation

Date of first enrolment
30/06/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Germany

Study participating centre
Balthasar-Neumann-Platz 1
Werneck
Germany
97444

Sponsor information

Organisation
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

Sponsor details
Willmar-Schwabe-Straße 4
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Sponsor type
Industry

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Dr Willmar Schwabe GmbH & Co. KG (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration