ISRCTN23790710 https://doi.org/10.1186/ISRCTN23790710

Stepwise ascending single-dose tolerability of Dulamin

Submission date
18/08/2011

Recruitment status
No longer recruiting

Registration date
02/09/2011

Overall study status
Completed

Last Edited
11/10/2011

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Uwe Fuhr

Contact details
Weyertal 76
Cologne
Germany
50931

Additional identifiers

Protocol serial number
561501.01.001

Study information

Scientific Title
A stepwise sequential dose-rising phase I study to assess the safety and tolerability of single p.o of 150mg to 2400 mg Dulamin in healthy subjects

Study objectives
The aim of this study is to evaluate the safety and tolerability of single p.o. doses of 150-2400mg Dulamin in healthy subjects

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, Medical Association of North Rhine, [Ethik-Kommission der Ärztekammer Nordrhein], 10 October 2011, ref: 2011311

Study design
Single centre, randomised, double-blind, placebo-controlled, dose-escalation study with oral single dose administration.

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Safety of Dulamin

Interventions
Single doses of 150 mg, 300 mg, 600 mg, 1200 mg, 1800 mg and 2400 mg Dulamin or placebo

Intervention Type
Drug

Phase
Phase I

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

Primary outcome(s)
1. Adverse events
2. Laboratory data
3. Blood pressure
4. Pulse rate
5. Electrocardiogram

Key secondary outcome(s))
Plasma pharmacokinetics

Completion date
23/01/2012

Eligibility

Key inclusion criteria
1. Age 18 - 55 years
2. Male

3. Caucasian
4. Informed consent
5. Healthy
6. Body mass index between 18 and 30 kg/m²

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. History or current evidence of clinically relevant allergies
2. History or current evidence of any clinically relevant diseases suspected to influence PKs of the IMP or safety of the subjects:
2.1. Cardiovascular
2.2. Pulmonary
2.3. Hepatic
2.4. Renal
2.5. Gastrointestinal
2.6. Haematological
2.7. Endocrinological
2.8. Metabolic
2.9. Neurological
2.10. Psychiatric
3. History of malignancy
4. Febrile or infectious illness within 5 days prior to administration of IMP
5. Chronic or clinically relevant acute infections
6. Proneness to orthostatic dysregulation, fainting, or blackouts
7. Positive results in any of the virology tests for:
7.1. HIV I and II-antibody (Ab)
7.2. Hepatitis B surface antigen (HbsAg)
7.3. Anti-HBV capsid (Hbc) immune globulins (Ig) (IgG + IgM)
7.4. HCV-Ab
8. Positive illicit drug screen
9. Positive alcohol breath test
10. Clinically relevant history or current evidence for abuse of alcohol (> 50 g/day ethanol) or drugs
11. Treatment with any agent known to induce/inhibit xenobiotic metabolising enzyme or transporter within 2 weeks prior to or during the study
12. Use of any medication (incl. over-the-counter medication) within 2 weeks before study drug administration or within less than 10 times the elimination half-life of the respective drug, or

anticipated concomitant medication during the treatment period
13. Consumption of any enzyme inducing or inhibiting aliments and beverages (e.g. broccoli, brussel sprout, grapefruit, grapefruit juice, St. John's Wort, star fruit etc.) within 72 hours prior to the start of the study
14. Consumption of any caffeine- or methylxanthine-containing product within 48 hours prior to the administration of IMP
15. Consumption of any flavonoid-containing product within 72 hours prior to the administration of IMP
16. Subjects with diseases or surgery of the gastrointestinal tract, which may interfere with drug absorption
17. Participation in drug studies within the last 30 days before administration of the IMP in the present study
18. Blood donation within the last 30 days before start of the study
19. Lack of ability or willingness to give informed consent
20. Vulnerable subjects (e.g. persons kept in detention)

Date of first enrolment
04/10/2011

Date of final enrolment
23/01/2012

Locations

Countries of recruitment
Germany

Study participating centre
Weyertal 76
Cologne
Germany
50931

Sponsor information

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

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type

Research organisation

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes