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# Stepwise ascending single-dose tolerability of Dulamin

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 18/08/2011 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 02/09/2011 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 11/10/2011 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Screening

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

## 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 measure

1. Adverse events
2. Laboratory data
3. Blood pressure
4. Pulse rate
5. Electrocardiogram

### Secondary outcome measures
Plasma pharmacokinetics

### Overall study start date
04/10/2011

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Male

### Target number of participants
24

### 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)

**Sponsor details**
Willmar-Schwabe-Straße 4
Karlsruhe
Germany
76227

**Sponsor type**
Research organisation

**Website**
http://www.schwabepharma.com/

**ROR**
https://ror.org/043rrkc78

# Funder(s)

**Funder type**
Research organisation

**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