# First-in-human phase I safety, pharmacokinetic, and pharmacodynamic study of G1T28-1 in healthy male and female subjects.

Published: 04-08-2014
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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Miscellaneous and site unspecified neoplasms benign |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON42109

**Source**
ToetsingOnline

**Brief title**
G1T28-1 SAD and PD study.

### Condition

- Miscellaneous and site unspecified neoplasms benign

**Synonym**
Cancer, chemotherapy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** G1 Therapeutics

**Source(s) of monetary or material Support:** Farmaceutische Industrie.

## Intervention

**Keyword:** Bone marrow cells, G1T28-1

## Outcome measures

### Primary outcome

Assess the safety and tolerability of G1T28-1 administered IV.

### Secondary outcome

Assess the pharmacokinetic (PK) profile of G1T28-1

Assess potential pharmacodynamic (PD) markers of G1T28-1

Define G1T28-1 dose(s) for further study

Assess the bioavailability of orally administered G1T28-1 in a separate cohort

of subjects

# Study description

### Background summary

G1T28-1 is a new investigational compound that may eventually be used for the prevention of chemotherapy-induced suppression of bone marrow cells. G1T28-1 will temporally block a protein that is responsible for the proliferation of bone marrow cells producing red and white blood cells. By blocking this protein, G1T28-1 will protect the bone marrow cells from chemotherapy and therefore some side effects like infection, bleeding or fatigue of chemotherapy may be reduced. This is the first time that this compound is being given to humans.

### Study objective

The purpose of the study is to investigate to what extent G1T28-1 is tolerated. It will also be investigated how quickly and to what extent G1T28-1 is absorbed and eliminated from the body (this is called pharmacokinetics). In addition, a possible effect of the compound on certain blood markers will be investigated (this is called pharmacodynamics).

The goals for analyzing the bone marrow in the current study are to:
* Provide critical pharmacodynamic (PD) information on the extent and duration of G0/G1
arrest of HSPCs following G1T28-1 administration.
* Correlate findings in the bone marrow with surrogate assays carried out in the peripheral blood
* Correlate PD findings in the bone marrow with pharmacokinetic (PK) data to develop
exposure-response (PK/PD) relationships of the effects of G1T28-1 in the bone marrow.

**Study design**

The study will consist of 1 dosing period during which the volunteer will receive G1T28-1 or placebo one time for Groups 1 to 6. In Group 7 only G1T28-1 will be administered. G1T28 1 and placebo will be given in the form of an intravenous infusion of 30 minutes.

Group 8: The actual study will consist of 3 periods. Each period you will stay in the clinical research center in Groningen for 5 days (4 nights) and each period will be followed by 2 days (Days 7 and 10) during which you will visit the clinical research center in Groningen. The time interval between the different periods is 3 days.

**Intervention**

Single and single-dose period G1T28-1 or placebo by intravenous infusion.

**Study burden and risks**

During the investigation, various assessments will be done that can be experienced as more or less stressfull.
Blood draw, intravenous infusion and for group 7 the decrease of bone marrow can be experienced as stressfull in this respect.

# Contacts

**Public**
G1 Therapeutics

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US
**Scientific**

G1 Therapeutics

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

healthy male or female
age 18 - 60 jaar, inclusive
BMI 18 - 32 kilogram/meter2
non smokers

## Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 3 months from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

# Study design

## Design

Study type: Interventional

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| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-08-2014 |
| Enrollment: | 58 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 04-08-2014 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 11-08-2014 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 04-12-2014 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 05-12-2014 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO | |

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| Date: | 13-01-2015 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 16-03-2015 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 17-03-2015 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

# 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 | EUCTR2014□002380□15-NL |
| CCMO | NL50159.056.14 |