# A RANDOMIZED, SINGLE DOSE, DOUBLE BLIND, PARALLEL GROUP, PHARMACOKINETIC TRIAL, COMPARING ONS-1045 (ONCOBIOLOGICS INC, USA) TO 2 ARMS OF AVASTIN® (GENENTECH, SOUTH SAN FRANCISCO, USA; ROCHE, SWITZERLAND) IN HEALTHY MALE VOLUNTEERS

Published: 01-12-2014
Last updated: 21-04-2024

Primary Objective:To demonstrate pharmacokinetic biosimilarity of ONS-1045 (Oncobiologics) to the EU- and US licensed product of Avastin® following a single 2.0 mg/kg i.v. infusion, in healthy male adult subjects.Secondary objective:• To evaluate...

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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-OMON41859

**Source**
ToetsingOnline

**Brief title**
Single dose study of ONS-1045 in healthy male volunteers.

### Condition

- Miscellaneous and site unspecified neoplasms benign

**Synonym**
Cancer

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Oncobiologics Inc
**Source(s) of monetary or material Support:** Oncobiologics Inc

## Intervention

**Keyword:** Avastin®, Bioequivalence, First-in-Human, Healthy volunteers

## Outcome measures

### Primary outcome

Primary endpoint is the following pharmacokinetic parameter:

• AUC0-* and ratio of the geometric least square means of test to reference

products and its associated 90% confidence interval

### Secondary outcome

Secondary pharmacokinetic endpoints include:

• Other pharmacokinetic parameters derived from serum samples including AUC0-t,

Cmax, Tmax, kel, t1/2el, clearance (CL), and Vd

Safety endpoints include:

• Adverse events (AE).

• Clinical laboratory and vital signs.

• Immunogenicity assessments.

# Study description

### Background summary

ONS-1045 is being developed as a biosimilar to Avastin® (bevacizumab) which is a recombinant human IgG1 monoclonal antibody specific for vascular endothelial growth factor (VEGF).

### Study objective

Primary Objective:
To demonstrate pharmacokinetic biosimilarity of ONS-1045 (Oncobiologics) to the EU- and US licensed product of Avastin® following a single 2.0 mg/kg i.v. infusion, in healthy male adult subjects.

Secondary objective:
• To evaluate the safety, tolerability, and immunogenicity of ONS-1045 (Oncobiologics) and the EU- and US-licensed product of Avastin® following a single 2.0 mg/kg i.v. infusion in healthy male adult subjects.

• To evaluate pharmacokinetic biosimilarity of the EU- to the US-licensed product of Avastin® following a single 2.0 mg/kg intravenous (i.v.) infusion, in healthy male adult subjects.

### Study design

single centre, double-blind, randomized, single-dose, 3-arm parallel study

### Intervention

A single dose of 2 mg/kg ONS-1045, EU-licensed Avastin® or US-licensed Avastin® will be administered

### Study burden and risks

The active substance of ONS-1045 is essentially the same biological substance as the marketed formulations of bevacizumab. Although there may be minor differences between ONS-1045 and bevacizumab, the experience with bevacizumab (Avastin) suggests that drugs of this class can be administered safely to healthy volunteers.
Avastin® EU and Avastin® US are widely used drugs and the most frequent reported side effects are gastrointestinal complaints (such as stomach ache, nausea and diarrhoea). Besides, blood pressure elevations and proteinuria have been described. As only a single (and lower) dose of bevacuzimab will be administered to the subjects in this study, the side effects are not expected

to happen. However, the subjects will be monitored closely during the conduct of the study to minimize risks

# Contacts

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**Scientific**
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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 subjects
- Age >=18 and <=55 years;
- Moderate to not smoking
- Body mass index 18.5- 30 kg/m2;
- Able and willing to give informed consent

## Exclusion criteria

- Clinical significant laboratory abnormalities
- Signs and symptoms of congestive Heart Failure;
- Presence of non-healing wound
- History of stroke
-Grade > 1 peripheral neuropathy (as defined by the NCI CTCAE, v3.0);
-History of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess within 6 months prior to study drug administration;

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 22-12-2014 |
| Enrollment: | 135 |
| Type: | Actual |

## Medical products/devices used

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| Product type: | Medicine |
| Brand name: | Avastin |
| Generic name: | Bevacizumab |
| Registration: | Yes - NL outside intended use |

# Ethics review

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| Approved WMO Date: | 01-12-2014 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 12-12-2014 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 16-01-2015 |
| 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 | EUCTR2014-004699-52-NL |
| CCMO | NL51376.056.14 |