# A randomized, double-blinded, placebo-controlled, single centre, phase I study of the safety of escalating single intravenous doses of NI-0801 in healthy volunteers.

Published: 07-07-2008
Last updated: 06-05-2024

To assess the safety and tolerability of escalating single IV doses of NI-0801.To determine the pharmacokinetics and pharmacodynamics parameters of escalating single IV doses of NI-0801.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Autoimmune disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33532

**Source**
ToetsingOnline

**Brief title**
Phase I study to investigate the safety of escalating i.v. doses of Ni-0801

### Condition

- Autoimmune disorders

**Synonym**
psoriasis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** NovImmune S.A.
**Source(s) of monetary or material Support:** NovImmune S.A.

## Intervention

**Keyword:** intravenous, NI-0801, Phase I, safety

## Outcome measures

### Primary outcome

Safety and tolerability of escalating single IV doses of NI-0801.

### Secondary outcome

Pharmacokinetics and pharmacodynamics parameters of escalating single IV doses

of NI-0801.

# Study description

### Background summary

Plasma and/or local IP-10 levels are upregulated in multiple autoimmune disorders and inflammatory diseases. NI-0801 is a fully human antibody capable of neutralizing human IP-10 with high affinity.

### Study objective

To assess the safety and tolerability of escalating single IV doses of NI-0801.
To determine the pharmacokinetics and pharmacodynamics parameters of escalating single IV doses of NI-0801.

### Study design

Randomized, double-masked, placebo-controlled, dose escalation.

### Intervention

Not applicable

**Study burden and risks**

The risks during this trial are the possible side effects related to the study medication.
Also the admission period, venapunctures and placing of the canula may cause a burden to the volunteers.

For each dose, two volunteers wil be dosed and only if there are no safety concerns, the following four volunteers wil be dosed. All volunteers are being monitored by experienced physicians and study personell.

## Contacts

**Public**
NovImmune S.A.

14 Chemin des Aulx
1228 Plan les Ouates
Switzerland
**Scientific**
NovImmune S.A.

14 Chemin des Aulx
1228 Plan les Ouates
Switzerland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

• written consent • men between 18 and 50 years old • physically en mentally healthy • normal BMI

### Exclusion criteria

• smoking • drugs and/or alcohol abuse • surgery within 3 months prior to study • use concomitant medication in two weeks prior to study • participation in another clinical study in 3 months prior to this study • Blood donation in 3 months prior to this study • positive for Hepatitis B, C or HIV • positive tuberculosis test • Vaccination within 6 weeks prior to start study medication

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-08-2008 |
| Enrollment: | 30 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | NI-0801 |
| Generic name: | n.v.t. |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 07-07-2008 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 01-08-2008 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 12-09-2008 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 26-11-2008 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 28-11-2008 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 23-02-2009 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |
| Approved WMO Date: | 04-03-2009 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

# 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 | EUCTR2008-003243-36-NL |
| CCMO | NL23900.040.08 |