# A Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous Injection of ABT-110 in Healthy Volunteers and Subjects with Chronic Low Back Pain

Published: 01-08-2012
Last updated: 26-04-2024

T\o evaluate the pharmacokinetics, safety and tolerability of the research medication

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Muscle disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36923

**Source**
ToetsingOnline

**Brief title**
ABT-110 M12-143

### Condition

- Muscle disorders

**Synonym**
chronic low back pain

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Abbott

**Source(s) of monetary or material Support:** Abbott

## Intervention

**Keyword:** Chronic low back pain, Single dose, Subcutaneous

## Outcome measures

### Primary outcome

Pharmacokinetics, safety and tolerability in healthy volunteers

### Secondary outcome

- Relative bioavailability of subcutaneously versus intravenously

administration of the study drug

- Pharmacokinetics, safety and tolerability in subjects with CLBP

# Study description

### Background summary

The research medication is a new medication under development for treatment of Chronic Low Back Pain (CLBP).

### Study objective

T\o evaluate the pharmacokinetics, safety and tolerability of the research medication

### Study design

This is a Phase 1, single center, open-label, randomized, parallel-group study

### Intervention

The study will start with a screening. At the screening a physical-, and neurological examination will take place and a few other standard medical assessments will be performed ( Vital Signs, ECG). Also a standard brief assessment of cognitive impairment (MMSE) will be performed. Furthermore a blood and urine sample will be taken for laboratory tests and an alcohol breath test and drug screen will be done.

For the CLBP group an x-ray will be performed and the subject's CLBP intensity will be assessed.

During the stay in the clinic the subject will receive the study medication and on several time points blood will be taken. Furthermore, a neurological examination will be performed as well as a standard brief assessment of cognitive impairment (MMSE). The subjects will be asked for possible side effects on a regular basis. Furthermore a drug screen will be performed and several safety assessments will be done frequently. For the CLBP group the subject's CLBP intensity will be assessed.

On ambulant visits blood will be collected, safety assessments will be done and CLBP intensity will be assessed for the CLBP group. Safety assessments will be done frequently.

Finally, a follow up visit will take place.

**Study burden and risks**

The safety and pharmacokinetics of ABT-110 has been investigated in one study in humans, administered intravenously (IV) to subjects with osteoarthritis (OA) of the knee. In that study, the dose was generally well-tolerated. Since the maximum administered dose in the present study is based on the ABT-110 first-in-human study it is expected that the research medication will be well-tolerated in the present study as well.
Side effects reported in the first ABT-110 study were headache, arthralgia, pain in extremity, myalgia, paraesthesia, nasopharyngitis, hyperaesthesia, hypoaesthesia, joint stiffness, joint swelling, dizziness, infusion related reaction, restless legs syndrome, fatigue, back pain,
burning sensation, hot flashes, nausea, osteoarthritis and oedema peripheral.

The maximum dose has been selected on a level, where risks for side effects are considered to be minimal, but unforseeable side effects could occur.

The blood collection may cause discomfort or bruising. Occasionally, fainting, an infection at the blood smpling site, bleeding and blood clot formation can occur.

# Contacts

**Public**
Abbott

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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 Volunteers: Male or female aged 18-55 years; females must be postmenopausal or surgically sterilized; BMI between 18 and 29 inclusive; general good health.
CLBP Subjects: Male or female aged 18-60 years; females must be postmenopausal or surgically sterilized; chronic pain located below 12th rib and above lower gluteal fold of at least 6 months duration and meeting protocol-specified pain severity criteria; must be currently taking an NSAID, atypical analgesic (e.g. tramadol or tapentadol), or opioid analgesic for CLBP with inadequate analgesia.

## Exclusion criteria

Healthy Volunteers: Any clinically significant medical problems.
CLBP Subjects: Any radiation of pain below the lower gluteal fold; any back injury within 3 months prior to study drug; history of back surgery within 1 year prior to study drug; radiographic evidence (x-ray) of osteoarthritis (OA) in any shoulder, hip or knee joint; history of osteonecrosis (avascular necrosis) or rapidly progressive OA in any joint; use of corticosteroids within the past year that meets protocol-specified criteria.

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 30 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | ABT-110 |
| Generic name: | ABT-110 |

# Ethics review

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| Approved WMO Date: | 01-08-2012 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

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| Approved WMO Date: | 09-08-2012 |
| Application type: | First submission |
| 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 | EUCTR2012-002505-21-NL |
| CCMO | NL41463.056.12 |