

# Adalimumab in low back pain

<b>Submission date</b> 01/09/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/05/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Lower back pain is a common problem, which affects most people at some point in their lives. Many people who experience LBP will recover quickly with no significant impact to their lives, but for some people the pain turns into a long term condition which can affect their ability to work. When a sufferer experiences episodes which last for at least three months, it is known as chronic lower back pain (CLBP). For some patients, their CLBP is caused by inflammation (swelling) in the vertebrae (small bones which make up the spine). Adalimumab is a medication used in patients with inflammatory conditions such as arthritis, as it works by reducing inflammation. The aim of this study is to investigate the effectiveness of treating patients who have CLBP caused by inflammation with adalimumab.

### Who can participate?

Adults with CLBP which is caused by inflammation.

### What does the study involve?

All participants receive a subcutaneous injection (injection under the skin) of 40mg Adalimumab every other week for 12 weeks. During this time, and for two weeks after the end of treatment, participants are asked to keep a record of any pain medication they take, which is reviewed at the start of the study, each time they have an injection and two weeks after the end of treatment. At the start of the study and then after 12 weeks, participants complete a number of questionnaires to assess their pain levels and disability. In addition, participants also have an MRI scan at the start of the study and after 12 weeks to measure the swelling (inflammation) in their spine).

### What are the possible benefits and risks of participating?

Participants may benefit from a reduction in pain and disability. There is a small risk that participants may be more vulnerable to developing an infection while taking the study drug.

### Where is the study run from?

1. University Hospital of Geneva (Switzerland)
2. HFR- Fribourg Cantonal Hospital (Switzerland)

### When is the study starting and how long is it expected to run for?

July 2010 to January 2015

Who is funding the study?

1. University Hospital of Geneva (Switzerland)
2. AbbVie (USA)

Who is the main contact?

Dr Stéphane Genevay  
stephane.genevay@hcuge.ch

## Contact information

### Type(s)

Scientific

### Contact name

Dr Stéphane Genevay

### ORCID ID

<http://orcid.org/0000-0003-4752-3186>

### Contact details

Division of Rheumatology  
University Hospitals of Geneva  
Geneva  
Switzerland  
1211  
+41 223 723 673  
stephane.genevay@hcuge.ch

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CE 10 139

## Study information

### Scientific Title

Anti-TNF treatment in patients with chronic low back pain associated with Modic I changes: An exploratory trial

### Study objectives

Adalimumab could be a potentiel treatment for low back pain patient with Modic I endplate changes.

Ethics approval required

Old ethics approval format

**Ethics approval(s)**

1. Ethical committee of Geneva University Hospital, 09/11/2011, ref: 10-139
2. Swissmedic, 16/12/2011, ref: 2011DR2213

**Study design**

Pilot one-arm non-randomised study

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**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**

Chronic low back pain patient with inflammatory pain pattern and Modic I endplate changes

**Interventions**

All patients receive a subcutaneous injection of Adalimumab 40mg every other week for 12 weeks.

Participants are asked to keep a pain medication diary from baseline until 2 weeks after the intervention, which is reviewed at baseline and then every 2 weeks until the final follow up 2 weeks after the intervention ends. Participants complete follow up questionnaires and undergo MRI scanning at 12 weeks.

**Intervention Type**

Drug

**Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

Adalimumab (Humira)

**Primary outcome measure**

Pain is measured using a numerical rating scale (NRS) and the Roland Disability Questionnaire (RDQ) at baseline and 12 weeks.

## **Secondary outcome measures**

1. Morning stiffness is measured using a numerical rating scale (NRS) at baseline and 12 weeks
2. Quality of sleep is measured using a numerical rating scale (NRS) at baseline and 12 weeks
3. Patient Global Improvement is measured using a numerical rating scale (NRS) at baseline and 12 weeks
4. Function is measured using Bath Ankylosing Spondylitis disease activity index (BASDAI) at baseline and 12 weeks
5. Health related quality of life is measured using the EuroQol-5 dimensions (EQ-5D) at baseline and 12 weeks
6. Pain medication taken is measured using the Pain Medication Diary at baseline and then every 2 weeks until 2 weeks post-intervention
7. Duration of sick listing is measured by questionnaire at baseline and 2 weeks post-intervention
8. Size of bone oedema is measured using MRI (Modic I) at baseline and 12 weeks

## **Overall study start date**

07/07/2010

## **Completion date**

23/01/2015

# **Eligibility**

## **Key inclusion criteria**

1. Age 18-65 years
2. Signed Informed Consent
3. Common low back pain
4. The presence of 2 out of 3 of the following points, indicating inflammatory back pain:
  - 4.1. Insidious onset
  - 4.2. Morning stiffness
  - 4.3. Improvement with exercise
5. Continuous pain for more than 3 months
6. Failure of at least one full course of non steroidal anti-inflammatory drug
7. Pain > 3/10 on a 0 to 10 numeric rating scale over the last 24 hours
8. At least one Modic I modification on lumbar MRI

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Upper age limit**

65 Years

## **Sex**

Both

## **Target number of participants**

25

## **Key exclusion criteria**

1. A diagnosis of spondylarthropathy following standard definition
2. Either : Presence of sacroiliitis on imaging  
or At least 2 of the following  
Inflammatory Bowel Disease, Arthritis, Enthesitis, Dactylitis, Uveitis, Psoriasis, Family history of spondylarthropathy, Elevated CRP or sedimentation rate
3. Radicular pain related to disc herniation
4. Neurogenic claudication related to lumbar stenosis
5. Comorbidities impairing with the evaluation of pain or function
6. Concomitant infection
  - 6.1. In case of tuberculosis (positive TBspot) at least one month of antituberculosis treatment is required before considering inclusion
  - 6.2. Active Hepatitis B infection (screening for active HBV infection will be performed)
7. Women of child-bearing age refusing to use contraceptive measure during the study, Pregnancy (pregnancy test will be performed before inclusion), breastfeeding
8. Heart failure (NYHA III and IV)
9. Current treatment with corticosteroids
10. Prior exposure to anti-TNF agents, including adalimumab
11. Inability to comply with the protocol requirements
12. Past history of cancer
13. Demyelinating diseases
14. Allergy to adalimumab or one of its components
15. Unable to read and understand the questionnaires (in French)
16. Poor motivation or other emotional or intellectual problems that are likely to limit the ability of the patient to comply with the protocol requirements

## **Date of first enrolment**

02/06/2013

## **Date of final enrolment**

24/10/2014

## **Locations**

### **Countries of recruitment**

Switzerland

### **Study participating centre**

**University Hospital of Geneva**

Division of Rheumatology

Geneva

Switzerland

1211

**Study participating centre****HFR- Fribourg Cantonal Hospital**

Department of Rheumatology, Physical Medicine and Rehabilitation

Fribourg

Switzerland

1708

## Sponsor information

**Organisation**

University Hospital of Geneva

**Sponsor details**

Perret-Gentil 4

Geneva

Switzerland

1211

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hug-ge.ch/>

**ROR**

<https://ror.org/01m1pv723>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

University Hospital of Geneva

**Funder Name**

AbbVie

**Alternative Name(s)**

AbbVie Inc., AbbVie U.S., AbbVie US, Allergan

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## **Results and Publications**

**Publication and dissemination plan**

Results will be presented in rheumatology and back pain congress. They will then be published in peer-reviewed journals.

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Available on request