



UiO : Universitetet i Oslo

***Acupuncture for acute non-specific low back pain:  
A protocol for a randomised controlled multicenter  
intervention study in general practice.***

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# Bakgrunn

- Vanlig problem i allmennpraksis.
- Allmennmedisinsk behandling.
- Medisinsk akupunktur.
- Klinisk erfaring.
- Dokumentasjon?



## Hypoteser - 1

- Akupunkturbehandling bidrar til **raskere smertereduksjon** ved akutte korsryggsmerter enn vanlig allmenmedisinsk behandling gitt i henhold til nasjonale retningslinjer.

## Hypoteser - 2

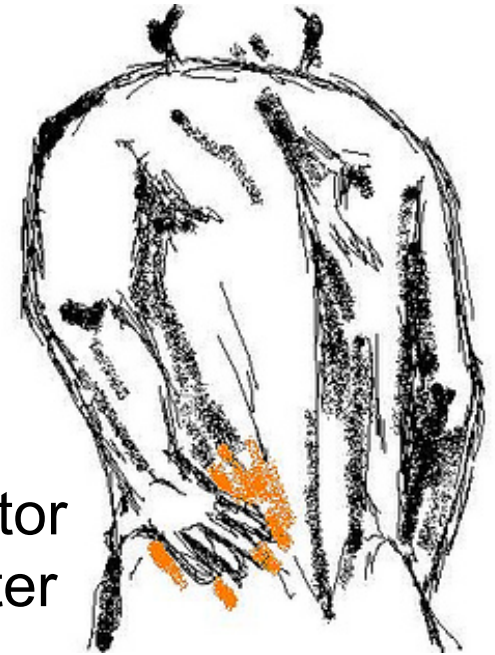
- Akupunkturbehandling ved akutte korsryggsmerter bedrer **funksjonsnivå**, reduserer **medikamentbruk** og **sykefravær**, sammenliknet med vanlig allmennt medisinsk behandling gitt i henhold til nasjonale retningslinjer.

## Hypoteser - 3

- Akupunkturbehandling ved akutte korsryggsmerter er en **kostnadseffektiv** behandling i allmennpraksis.

# Deltakere

- **Inklusjonskriterier:**
  - 20-55 år som tar kontakt med sitt fastlegekontor på grunn av akutte uspesifikke korsryggsmerter (0-14 dager)
- **Eksklusjonskriterier:**
  - Nerverotsaffeksjon / utstrålende smerter nedenfor kneet
  - "Røde flagg"
  - Svangerskap
  - Sykefravær (>14 dager siste måned)
  - Uføretrygd



## Multisenter studie

- 11 legekontorer i Sør-Norge
- En gruppe leger behandler kontrollgruppen
- En annen gruppe leger behandler intervensjonsgruppen



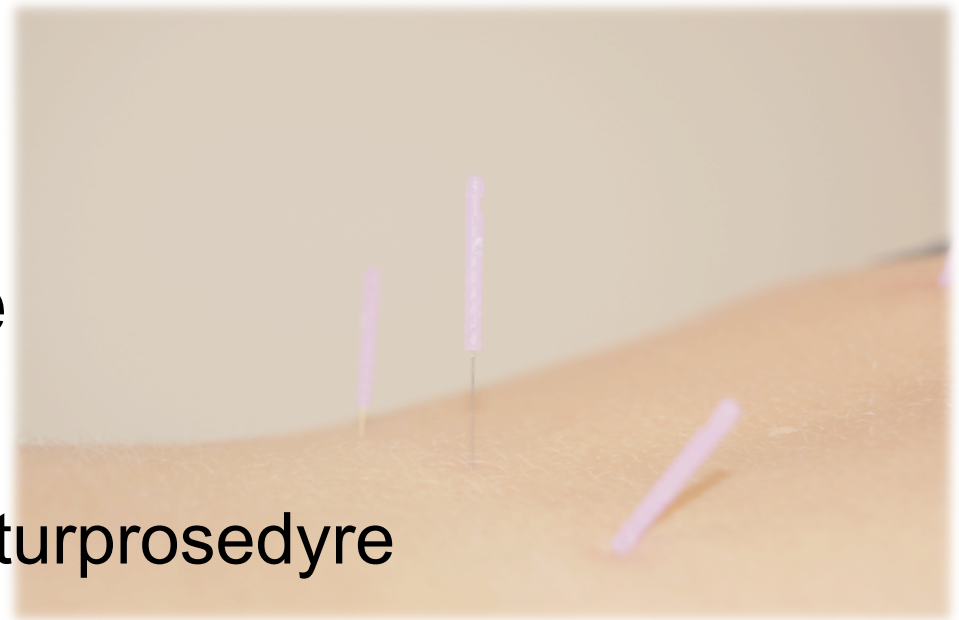
## Kontrollgruppe

- Vanlig allmenntilleggsmedisinsk behandling etter Nasjonale retningslinjer,
- Dvs. råd om generell aktivitet, smertestillende (Paracet + ev. Ibux og ev. Tramadol), samt ev. sykmelding.
- Måler konsultasjonstiden i begge grupper.





## Akupunkturgruppe



- Som kontroll + akupunkturprosedyre
- I stol: 2 akupunkturpunkter i høy hånd, stimuleres i totalt 1 min.
- Roterende bekkenbevegelser i totalt 2 min.
- På benk: 6 akupunkturpunkter i nivå L2-L4.
- Etter 5 min tas alle nålene ut, totalt ca 8 minutter.
- Noe av beh.tiden brukes til å gi råd, skrive resepter og journalnotat.

## Primært resultatmål

- Median tid i dager til tilfriskning av smerte, målt første dagen pas. scorer 0 eller 1 på Numerical Rating Scale (NRS) fra 0 til 10.
- Klinisk relevant forskjell: 3 dager

2a Hvor intense er ryggsmertene dine i dag?

*ingen smerter*

*de verste smertene  
jeg kan forestille meg*

0 1 2 3 4 5 6 7 8 9 10

## Sekundære resultatmål

- Smerte, målt ved NRS fra 0-10.
- Global måling av bedring (Likert scale).
- Ryggspesifikk funksjonell status (Roland Morris Disability Questionnaire).
- Sykefravær.
- Bruk av medisiner (Paracet og ev. andre).
- Antall nye legebesøk.
- Bivirkninger av behandling.

## Måleverktøy

- Numerical rating scale (NRS) 0-10 (Smerte)
- Likert scale, 1-5 (Global bedring)
- Roland Morris Disability Questionnaire (RDQ) (Ryggfunksjon)
- EQ-5D (Helserelatert livskvalitet)
- Sosiodemografiske variabler
- Örebro screening ("Gule flagg")
- Subjective Health Complaints (SHC)

## Randomisering

- 2 grupper, 135 i hver.
- Datagenerert randomisert tabell, webbasert.
- Randomisering skjer hos helsesekretær før timen settes opp.
- Pasienten vet ikke hvilken gruppe han/hun er i før etter utfylling av baseline-skjema.
- Interimsanalyse etter 150 pasienter.





## Acupuncture for acute non-specific low back pain: a protocol for a randomised, controlled multicentre intervention study in general practice—the Acuback Study

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# Progresjon

- Protokoll publisert BMJ Open, juni 2012
- Godkjent av REK, april 2013
- Finansiert av Avdeling for allmennmedisin, UiO
- Gidske og Peter Jacob Sørenses forskningsfond: 100.000 kr!
- Pilotstudie høsten 2013: 8 pasienter
- Workshop med deltakende legekontorer: Nå!
- Hovedstudie starter 17. mars 2014

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### ABSTRACT

**Introduction:** Some general practitioners (GPs) treat acute low back pain (LBP) with acupuncture, despite a lack of evidence for its effectiveness. This study will evaluate whether acupuncture can reduce time to recovery when applied in addition to standard LBP treatment according to the Norwegian national guidelines. Analyses of prognostic factors for recovery and cost-effectiveness will also be carried out.

**Methods and analysis:** In this randomised, controlled multicentre study in general practice in Southern Norway, 270 patients will be allocated into one of two treatment groups, using a web-based application based on block randomisation. Outcome assessment will be blinded for group allocation of the patients. The primary outcome is the median time to recovery (in days). The secondary outcomes are rated global improvement, back-specific functional status, sick leave, medication, GP visits and side effects. A pilot study will be conducted.

**Ethics and dissemination:** Participation is based on informed written consent. The authors will apply for an ethical approval from the Regional Committee for Medical and Health Research Ethics when the study protocol is published. Results from this study, positive or negative, will be disseminated through the medical journal *BMJ Open*. The trial is registered with ClinicalTrials.gov Identifier: NCT01439412.

### ARTICLE SUMMARY

#### Focus

Does acupuncture treatment contribute to faster recovery in acute LBP compared with standard treatment in general practice provided in accordance with the Norwegian national guidelines?

- Does acupuncture treatment for acute LBP improve function and reduce drug use and sick leave?
- Is acupuncture treatment for acute LBP a cost-effective treatment in general practice?

#### Key messages

- This project will increase the knowledge about the effects of acupuncture treatment for acute LBP.
- The methodology of the trial is stronger than previous studies.
- A faster pain relief will aid the patients to earlier return to normal, everyday activities, including return to their work.

#### Strengths and limitations of this study

- The methodology of the trial is stronger than previous studies.
- There are still methodological challenges in acupuncture trials, in this trial, neither the patient or the GP will be blinded, and the consultation time will be longer in the intervention group.

### INTRODUCTION

Low back pain (LBP) is a very common disorder with consequences for the individual patient as well as for the society. Up to 80% of the population experiences back pain at least once in their lifetime, about 50% during the previous year. Point prevalence is 15%, and the condition relapses frequently, 40% within 6 months. Back pain is the leading cause of disability in terms of lost work days in most industrialised countries.

## Hvem er med?

- *Holgeir Skjeie*, spes. allmennmedisin, Kristiansand
- **Veiledere:**
  - *Arne Fetveit* og *Mette Brekke*, Avd. for allmennmedisin, UiO
- **Samarbeid med:**
  - FORMI: *Margreth Grotle*
  - Karolinska Institutet: *Irene Lund* (virkningsmekanismer)
  - Keele University (prognostiske faktorer, kost-nytte)

The logo for ACUBACK is displayed in a green, stylized font. The letters are arranged horizontally across the center of the image. The background is a close-up photograph of human skin with a medical needle inserted. The needle's tip is positioned directly behind the letter 'U'. The skin is a warm, orange-brown color, and the needle is a thin, metallic wire with a pink cap. The overall image has a soft, slightly blurred quality, focusing attention on the text and the needle's placement.

ACUBACK

# Takk for oppmerksomheten!



search ID: vsh0682

"Hey! My lower back pain! It's gone!"