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Supervised Exercises Compared With Radial Extracorporal Shock Wave Therapy (rESWT) in Patients With SIS

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT00653081

Recruitment Status : Unknown
Verified January 2007 by Ullevaal University Hospital.
Recruitment status was: Active, not recruiting
First Posted : April 4, 2008
Last Update Posted : April 4, 2008

Sponsor:
Ullevaal University Hospital

Collaborators:
South Eastern Area Health Service
University of Oslo

Information provided by:
Ullevaal University Hospital

Study Description

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Brief Summary:
The purpose of this study is to compare Supervised Exercises with another non-operative frequently used treatment, Radial Extracorporeal Shockwave Therapy (rESWT), for patients with subacromial impingement syndrome.

Condition or disease	Intervention/treatment	Phase
Shoulder Pain	Procedure: Physical therapy method called Supervised Exercises Procedure: Radial Extracorporeal Shockwave Therapy	Phase 3

Detailed Description:

Shoulder pain is, in succession to back, neck, and knee, the fourth most frequently localized musculoskeletal pain reported by patients to general practitioners and physical therapists. A majority of shoulder complaints lasts for more than three months and become chronic. Few of the different interventions for rehabilitation of chronic shoulder pain, have documented effect. Patients with shoulder pain are associated with significant disability and loss of quality of life which interfere with activities related to daily living.

Supervised exercises, a treatment method which has been compared to surgery and placebo laser, is one that has documented effect for both short (6 months) and long time (2½ years). The purpose of this study was to compare Supervised Exercises with another non-operative common used treatment method for these patients, radial Extracorporeal Shockwave Therapy (rESWT).

The study is designed as a randomised, single blind clinical controlled study.

Study Design

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Study Type :
Interventional (Clinical Trial)

Actual Enrollment :
104 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

Masking:
Single (Outcomes Assessor)

Primary Purpose:
Treatment

Official Title:
Supervised Exercises Compared With Radial Extracorporal Shock Wave Therapy (rESWT) in Patients With Subacromial Impingement Syndrome: A Single Blind Clinical Randomized Study

Study Start Date :

July 2006

Actual Primary Completion Date :

September 2007

Estimated Study Completion Date :

December 2008

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Exercise and Physical Fitness Shock

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Active Comparator: A Supervised Exercises performed at ulleval Hospital for patients with shoulder pain. Dosage: 45 minutes each time, max 2-3 times a week in max 12 weeks	Procedure: Physical therapy method called Supervised Exercises Performed at ullevaal Hospital, 45 min each time, 2-3 times pr week in max 12 weeks
Active Comparator: B Radial Shock Wave therapy performed at ulleval Hospital, once a week, 4-6 times, 3-5 points each time.	Procedure: Radial Extracorporeal Shockwave Therapy Radial Shock Wave therapy performed at ulleval Hospital, once a week, 4-6 times, 3-5 points each time.

Outcome Measures

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Primary Outcome Measures :

1. Shoulder Pain and Disability Index (SPADI) [Time Frame: Baseline, 6 weeks, 12 weeks, 18 weeks and 12 months]

Secondary Outcome Measures :

1. Pain intensity labelled "no pain" and "severe pain" at its extremes, are measured on nine point scales for activity and rest during last week. [Time Frame: Baseline, 6 weeks, 12 weeks, 18 weeks and 12 months]

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years to 70 Years (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Subacromial shoulder pain lasting for at least three months and age between 18 and 70 years.
- Dysfunction or pain on abduction
- Had a normal passive glenohumeral range of movement
- Pain during two of three isometric tests (abduction, external- or internal rotation at 0º or 30º)
- Positive Hawkins-Kennedys test.

Exclusion Criteria:

- Shoulder pain bilateral (both shoulders required treatment)
- Earlier operated in affected shoulder
- Had multidirectional instability
- Had the cervical syndrome
- Rheumatoid arthritis

- Clinical and radiological findings indicating glenohumeral - or acromioclavicular joint pathology
- Not able to understand spoken or written Norwegian
- Considerable emotional distress
- Needed anticoagulant medicine
- Being pregnant
- Had had Shock Wave Therapy or Supervised Exercises before.

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT00653081***

Locations

Norway

Department for physical medicine and rehabilitation, Ullevaal University Hospital
Oslo, Norway, 0407

Sponsors and Collaborators

Ullevaal University Hospital

South Eastern Area Health Service

University of Oslo

Investigators

Principal Investigator: Kaia Engebretsen, PhD Dep of Physical Medicine and rehabilitation, Ullevaal Universi

More Information

Go to

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Engebretsen K, Grotle M, Bautz-Holter E, Ekeberg OM, Juel NG, Brox JI. Supervised exercises compared with radial extracorporeal shock-wave therapy for subacromial shoulder pain: 1-year results of a single-blind randomized controlled trial. Phys Ther. 2011 Jan;91(1):37-47. doi: 10.2522/ptj.20090338. Epub 2010 Nov 18.

Engebretsen K, Grotle M, Bautz-Holter E, Ekeberg OM, Brox JI. Predictors of shoulder pain and disability index (SPADI) and work status after 1 year in patients with subacromial shoulder pain. BMC Musculoskelet Disord. 2010 Sep 23;11:218. doi: 10.1186/1471-2474-11-218.

Engebretsen K, Grotle M, Bautz-Holter E, Sandvik L, Juel NG, Ekeberg OM, Brox JI. Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: single blind randomised study. BMJ. 2009 Sep 15;339:b3360. doi: 10.1136/bmj.b3360.

Responsible Party:

University of Oslo, South Eastern Area Health Service

ClinicalTrials.gov Identifier:

NCT00653081 History of Changes

Other Study ID Numbers:

VT

rESWT

First Posted:

April 4, 2008 Key Record Dates

Last Update Posted:

April 4, 2008

Last Verified:

January 2007

Keywords provided by Ullevaal University Hospital:

Shoulder pain

Supervised Exercises

Radial Shock Wave Therapy

Additional relevant MeSH terms:

Shoulder Pain

Arthralgia

Joint Diseases

Musculoskeletal Diseases

Pain

Neurologic Manifestations

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Supervised Exercises Compared With Radial Extracorporal Shock Wave Therapy (rESWT) in Patients With SIS

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Last Update Posted : April 4, 2008

Sponsor:
Ullevaal University Hospital

Collaborators:
South Eastern Area Health Service
University of Oslo

Information provided by:
Ullevaal University Hospital

Tracking Information

First Submitted Date ICMJE
January 7, 2008

First Posted Date ICMJE

April 4, 2008

Last Update Posted Date

April 4, 2008

Study Start Date ICMJE

July 2006

Actual Primary Completion Date

September 2007 (Final data collection date for primary outcome measure)

Current Primary Outcome Measures ICMJE
(submitted: April 3, 2008)

Shoulder Pain and Disability Index (SPADI) [Time Frame: Baseline, 6 weeks, 12 weeks, 18 weeks and 12 months]

Original Primary Outcome Measures ICMJE

Same as current

Change History

No Changes Posted

Current Secondary Outcome Measures ICMJE
(submitted: April 3, 2008)

Pain intensity labelled "no pain" and "severe pain" at its extremes, are measured on nine point scales for activity and rest during last week. [Time Frame: Baseline, 6 weeks, 12 weeks, 18 weeks and 12 months]

Original Secondary Outcome Measures ICMJE

Same as current

Current Other Pre-specified Outcome Measures

Not Provided

Original Other Pre-specified Outcome Measures

Not Provided

Descriptive Information

Brief Title ICMJE

Supervised Exercises Compared With Radial Extracorporal Shock Wave Therapy (rESWT) in Patients With SIS

Official Title ICMJE

Supervised Exercises Compared With Radial Extracorporal Shock Wave Therapy (rESWT) in Patients With Subacromial Impingement Syndrome: A Single Blind Clinical Randomized Study

Brief Summary

The purpose of this study is to compare Supervised Exercises with another non-operative frequently used treatment, Radial Extracorporeal Shockwave Therapy (rESWT), for patients with subacromial impingement syndrome.

Detailed Description

Shoulder pain is, in succession to back, neck, and knee, the fourth most frequently localized musculoskeletal pain reported by patients to general practitioners and physical therapists. A majority of shoulder complaints lasts for more than three months and become chronic. Few of the different interventions for rehabilitation of chronic shoulder pain, have documented effect. Patients with shoulder pain are associated with significant disability and loss of quality of life which interfere with activities related to daily living.

Supervised exercises, a treatment method which has been compared to surgery and placebo laser, is one that has documented effect for both short (6 months) and long time (2½ years). The purpose of this study was to compare Supervised Exercises with another non-operative common used treatment method for these patients, radial Extracorporeal Shockwave Therapy (rESWT).

The study is designed as a randomised, single blind clinical controlled study.

Study Type ICMJE

Interventional

Study Phase ICMJE

Phase 3

Study Design ICMJE

Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Single (Outcomes Assessor)
Primary Purpose: Treatment

Condition ICMJE

Shoulder Pain

Intervention ICMJE

- Procedure: Physical therapy method called Supervised Exercises

  Performed at ullevaal Hospital, 45 min each time, 2-3 times pr week in max 12 weeks

- Procedure: Radial Extracorporeal Shockwave Therapy

  Radial Shock Wave therapy performed at ulleval Hospital, once a week, 4-6 times, 3-5 points each time.

Study Arms ICMJE

- Active Comparator: A

  Supervised Exercises performed at ulleval Hospital for patients with shoulder pain. Dosage: 45 minutes each time, max 2-3 times a week in max 12 weeks

  Intervention: Procedure: Physical therapy method called Supervised Exercises

- Active Comparator: B

  Radial Shock Wave therapy performed at ulleval Hospital, once a week, 4-6 times, 3-5 points each time.

  Intervention: Procedure: Radial Extracorporeal Shockwave Therapy

Publications *

- Engebretsen K, Grotle M, Bautz-Holter E, Ekeberg OM, Juel NG, Brox JI. Supervised exercises compared with radial extracorporeal shock-wave therapy for subacromial shoulder pain: 1-year results of a single-blind randomized controlled trial. Phys Ther. 2011 Jan;91(1):37-47. doi: 10.2522/ptj.20090338. Epub 2010 Nov 18.
- Engebretsen K, Grotle M, Bautz-Holter E, Ekeberg OM, Brox JI. Predictors of shoulder pain and disability index (SPADI) and work status after 1 year in patients with subacromial shoulder pain. BMC Musculoskelet Disord. 2010 Sep 23;11:218. doi: 10.1186/1471-2474-11-218.
- Engebretsen K, Grotle M, Bautz-Holter E, Sandvik L, Juel NG, Ekeberg OM, Brox JI. Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: single blind randomised study. BMJ. 2009 Sep 15;339:b3360. doi: 10.1136/bmj.b3360.

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE

Unknown status

Actual Enrollment ICMJE
(submitted: April 3, 2008)

104

Original Actual Enrollment ICMJE

Same as current

Estimated Study Completion Date ICMJE

December 2008

Actual Primary Completion Date

September 2007 (Final data collection date for primary outcome measure)

Eligibility Criteria ICMJE

Inclusion Criteria:

- Subacromial shoulder pain lasting for at least three months and age between 18 and 70 years.
- Dysfunction or pain on abduction
- Had a normal passive glenohumeral range of movement
- Pain during two of three isometric tests (abduction, external- or internal rotation at 0º or 30º)
- Positive Hawkins-Kennedys test.

Exclusion Criteria:

- Shoulder pain bilateral (both shoulders required treatment)
- Earlier operated in affected shoulder
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- Clinical and radiological findings indicating glenohumeral - or acromioclavicular joint pathology
- Not able to understand spoken or written Norwegian
- Considerable emotional distress
- Needed anticoagulant medicine
- Being pregnant
- Had had Shock Wave Therapy or Supervised Exercises before.

Sex/Gender ICMJE

Sexes Eligible for Study:

All

Ages ICMJE

18 Years to 70 Years (Adult, Older Adult)

Accepts Healthy Volunteers ICMJE

No

Contacts ICMJE

Contact information is only displayed when the study is recruiting subjects

Listed Location Countries ICMJE

Norway

Removed Location Countries

Administrative Information

NCT Number ICMJE

NCT00653081

Other Study ID Numbers ICMJE

VT
rESWT

Has Data Monitoring Committee

Yes

U.S. FDA-regulated Product

Not Provided

IPD Sharing Statement ICMJE

Not Provided

Responsible Party

University of Oslo, South Eastern Area Health Service

Study Sponsor ICMJE

Ullevaal University Hospital

Collaborators ICMJE

- South Eastern Area Health Service
- University of Oslo

Investigators ICMJE

Principal Investigator:

Kaia Engebretsen, PhD

Dep of Physical Medicine and rehabilitation, Ullevaal University Hospital, Oslo, Norway

PRS Account

Ullevaal University Hospital

Verification Date

January 2007

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**