

The effect of a newly developed patch treatment for disc hernia

Submission date 12/12/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/01/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Treatment of low back pain and neck pain in cases of disc hernia involves drugs, physical therapy and surgery in severe cases. This new drug is a patch that is easy to apply by sticking onto the skin. The aim of this study is to find out if this patch treatment is effective in reducing low back pain or neck pain due to disc hernia.

Who can participate?

Any patient suffering from back and neck pain aged between 20 to 60 years can take part in the study. Healthy volunteers of the same age range can also take part in the study.

What does the study involve?

Patients will be given the patch treatment if the pain is not resolved by drugs or physical therapy. We will also give the patch to healthy participants for comparison. Participants will have to rest completely during treatment. Pain before and after the treatment will be measured. Patients will also undergo a magnetic resonance examination before and after the treatment.

What are the possible benefits and risks of participating?

The most important side effect of the treatment is local rash in the skin where the patch is attached. There are no other side effects expected from the patch.

Where is the study run from?

Neurosurgery Department of Yildirim Beyazit Education and Research Hospital, Turkey.

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

The study will run between January 2014 and February 2014.

Who is funding the study?

Metuas Medical Company, Turkey.

Who is the main contact?

Dr Mehmet Sorar
msorar@gmail.com

Contact information

Type(s)

Scientific

Contact name

Dr Gulsah Bayram Kabacam

Contact details

Bagcilar Mah. Acin Cad. 281. Sok 3/10 GOP
Ankara
Türkiye
06670

Additional identifiers

Protocol serial number

ARTC0001CL

Study information

Scientific Title

A pilot controlled study on the efficacy of a diffusional patch (ArtCure®) for the treatment of disc hernia

Study objectives

Artcure diffusional patch is safe and effective for the treatment of disc hernia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kecioren Education and Research Hospital board of ethics, 15/03/2012, ref: 15.03.2012/B.10.4. İSM.4.06/68/49

Study design

Single-center controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Disc hernia/low back pain/neck pain

Interventions

Artcure patch treatment with complete bed rest in disc hernia and healthy control cases.

All of the cases admitted to the hospital with cervical or lumbar disc herniation that is resistant to medical and physical therapy will be taken into the study if they fill in the informed consent form. Pre-treatment neurological examination and semi-quantitative, subjective pain assessment using the Visual Analog Scale (VAS) scoring from 0 (no pain) to 10 (most severe pain) will be carried out. Diagnosis and extent of the hernia will be confirmed by MRI examination. The Artcure® diffusional patch will be attached to the level of herniation, taking care that the central part of the patch is at the same level as the hernia. Patients then have 24 hours of absolute bed rest. At the end of this period the patch will be removed. Post-treatment assessment will be comprised of a second neurological examination. VAS scores for pain assessment will be determined 24 and 48 hours after the treatment. Control MRI examinations with the same sequences will be done in 6-8 weeks post-treatment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Complete resolution of the pain [48 hours post-treatment visual analogue scale (VAS) score = 0]
2. More than 5 points decrease in the VAS score in the 48 hours post-treatment
3. Complete resolution of the neurologic deficit in 48 hours

Key secondary outcome(s)

1. VAS and neurological examinations will be performed at the baseline, 24 and 48 hours after the treatment
2. Pre- and post-treatment MRIs will be taken before the treatment and 6-8 weeks after the treatment

Completion date

01/02/2014

Eligibility

Key inclusion criteria

1. Patients with severe low back or neck pain due to disc hernia between the ages of 20 and 60 who are willing to take part
2. Age-matched healthy control cases without low back pain and disc hernia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Severe para-vertebral muscle spasm
2. Lumbar spinal stenosis
3. Foraminal stenosis
4. Calcified lumbar or cervical hernia
5. Loss of cervical or lumbar lordosis accompanying disc hernia
6. Loss of strength in any muscle group more than 2/5
7. Known dermal atrophy
8. Accompanying asthma

Date of first enrolment

01/01/2014

Date of final enrolment

01/02/2014

Locations

Countries of recruitment

Türkiye

Study participating centre

Bagcilar Mah. Acin Cad. 281. Sok 3/10 GOP
Ankara
Türkiye
06670

Sponsor information

Organisation

Metuas Medical Company (Turkey)

Funder(s)

Funder type

Industry

Funder Name

Metuas Medical Company (Turkey)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration