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The effect of a newly developed patch treatment for disc hernia

Submission date	Recruitment status	[ ] Prospectively registered
12/12/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/01/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/01/2014	Musculoskeletal Diseases	[ ] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

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
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 measure
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

Secondary outcome measures
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

Overall study start date
01/01/2014

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

Age group
Adult

Sex
Both

Target number of participants
40 patients and 40 control cases

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 atophy
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
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Sponsor information

Organisation
Metuas Medical Company (Turkey)

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Metuas Medical Company (Turkey)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration