Spontaneous contraction pattern of the Transverse Abdominal muscle in pregnancy-related low back pain

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Primary research question part 1: "Is it possible, to find a difference between the contraction pattern of the abdominal muscles measured with ultrasound between pregnant women with and without low back pain?*Primary research question part 2:...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33546

Source
ToetsingOnline

Brief title
TA use in low back pain

Condition

- Joint disorders

Synonym
back pain; non-specific low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Annafonds en Pavarotti Ahoy foundation

Intervention

Keyword: Back Pain, Coordination, Pregnancy, Ultrasound

Outcome measures

Primary outcome

To be able to answer the primary research question part 1 the following primary study parameters will be used:

- the thickness (in mm) of the three abdominal muscles in the lateral part of the abdominal wall during rest and during 5 described test situations.

- the answer on the question: *Did you feel pain in the low back region during the past week? (Yes / No).

- the place were the pain is indicated on a drawing

To be able to answer the primary research question part 2 the following extra primary study parameters will be used:

- the severity of pain measured on an 11-points Numeric Analog Scale.

- the severity of pain-related disability measured with the Dutch version of the Quebec Back Pain Disability Scale.

- the score on the ASLR-test (range 0-10)

Secondary outcome

To be able to answer the secondary research question the following extra

primary study parameters will be used:

- the severity of pain measured on an 11-points Numeric Analog Scale (score 4

and higher).

- the score on the ASLR-test (negative or positive).

- the score for the Posterior Pelvic Pain Provocation test (negative or

positive).

Study description

Background summary

The incidence of low back pain is high. In 85% the cause is unclear. In those 85% the back pain is labeled as non-specific, and causal treatment is impossible. Research has shown that the contraction pattern of the transverse abdominal muscle (TA, the deepest of the three muscles of the lateral part of the abdominal wall) in patients with non-specific low back pain differs from that of subjects without low back pain. Investigations by means of EMG have shown that in patients with low back pain TA contraction is delayed. It seems credible to assume that this changed contraction pattern reduces the strength of the pelvic ring and the lumbar spine and seems to be one of the factors that causes delayed recovery of back pain. In diagnosis and treatment a need exists for a patient-friendly, reliable, sensitive and specific method to check the contraction pattern of the TA in subjects with back pain. Currently the judgment of the therapist is based upon inspection, palpation and sonography of the abdomen. Reliability of inspection and palpation are low. Sonography to measure the thickness of the abdominal muscles is very reliable. However, the thickness at rest in patients with back pain is about the same as in controls. Some studies show a difference of TA thickness of patients compared to controls in special test situations e.g. during a drawing in maneuver of the abdomen. Problems are 1) the differences between patients and controls are small and 2) some other studies are not able to confirm the results.
The studies of the TA by means of ultrasound in patients with back pain show several drawbacks such as: possible confounders as cause, duration and severity of the pain are not considered, controls are recruited from a different population than the patients; contraction pattern of the abdominal muscles is studied at rest and/or after the instruction to tense the abdominal muscles instead of the spontaneous contraction pattern during activities which burden the lumbar spine. In the proposed study attempts were made to cope with these shortcomings. It is also for these reasons that de study focuses on back pain

during pregnancy. Primary the study is explorative. In further studies the use of possible positive findings should be tested in other patients groups than pregnant women.

Study objective

Primary research question part 1:
"Is it possible, to find a difference between the contraction pattern of the abdominal muscles measured with ultrasound between pregnant women with and without low back pain?*

Primary research question part 2:
"Is it possible within a group of pregnant women with low back pain to find a correlation between the contraction pattern of the abdominal muscles measured with ultrasound and severity of back pain and disability?*

Secondary research question
In a subgroup analysis part 1 of the primary research question is asked again for patients with severe pain in combination with positive scores for pelvic girdle pain.
So:
"Is it possible, to find a difference between the contraction pattern of the abdominal muscles measured with ultrasound between pregnant women with severe low back pain and positive scores for tests for pelvic girdle pain and controls without low back pain and negative scores for pelvic girdle pain?*

Study design

Cross-sectional study

Study burden and risks

1. Examination: 5 minutes
2. Ultrasound examination: 10 minutes
3. Fill in questionnaires: 5 minutes (healthy control)-10 minutes (patient)
The investigation is hardly irritating and is without any risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

uncomplicated singleton pregnancy, in week 20-30;

Exclusion criteria

Insufficient knowledge of Dutch language to fill in questionnaires; low back pain with a specific cause; systemic disorders of the neuromuscular system; arthritis of spine and/or hips; severe disturbance of anatomy of back, pelvis and/or abdomen (congenital, by trauma, surgery or adipositas); severe psychopathology.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2010
Enrollment:	80
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	10-09-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL23627.078.08