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Effects of Kinesio Taping over stretched abdominal muscles following pregnancy

Submission date
01/12/2020

Recruitment status
No longer recruiting

Registration date
23/12/2020

Overall study status
Completed

Last Edited
17/01/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Abdominal rectus diastasis (RAD) is when the tummy muscles over-stretch during pregnancy and separate down the midline.
This study will investigate the use of different types of tape to control RAD following pregnancy.

Who can participate?
Women with RAD following childbirth

What does the study involve?
The participants are randomly assigned to one of two groups: the KT group (intervention), in which KT tapes were applied, and the sham KT group (control, sham intervention), in which non-stretch tapes were used (cloth surgical tape). In all participants, a palpation assessment of RAD was conducted and the inter-recti distance was measured using a digital caliper at three sites, at the umbilicus and 4.5 cm above and below it.

What are the possible benefits and risks of participating?
Benefits: getting to know the possibilities of RAD treatment, possible therapeutic benefits after using Kinesio Taping tapes. Risks: skin allergies from the use of tapes.

Where is the study run from?
Wroclaw Medical University (Poland)

When is the study starting and how long is it expected to run for?
December 2017 to December 2021

Who is funding the study?
Ministry of Science and Higher Education in Poland

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SUB.E060.19.001

Study information

Scientific Title
Effects of Kinesio Taping on rectus abdominis diastasis in postpartum women

Acronym
KTonRAD

Study objectives
The primary objective of this study is a palpation assessment of rectus abdominis diastasis (RAD) in postpartum women before and after the application of Kinesio Taping (KT) tapes and a subsequent comparison of the results with those from a sham intervention group. The expectation is that RAD will decrease due to the application of KT tapes. A secondary objective is an electromyographic assessment of the effect of Kinesio Taping on the rectus abdominis. The hypothesis is that the bioelectrical activity of the muscles will increase as a result of the KT tapes application.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/12/2017, Institutional Review Board at Wroclaw Medical University (ul. Pasteura 1, 50-367 Wrocław, Poland; +48 71 784 17 10; bioetyka@umed.wroc.pl), ref: KB – 43/2018

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Rectus abdominis diastasis (RAD) in postpartum women

Interventions
The participants were randomly assigned to one of two groups: the KT group (intervention), in which KT tapes were applied, and the sham KT group (control, sham intervention), in which non-stretch tapes were used (cloth surgical tape). The application of KT tapes in the intervention group, using the corrective (mechanical) technique with a 75 - 100% tension range. In the control group, non-stretch tapes were used (cloth surgical tape). The tapes were placed perpendicularly to the rectus abdominis in the form of 2.5 cm-wide strips along the entire length of the muscle, crossing the midline of the linea alba. The application period was 48 hours. After that time, the tapes were removed and the measurements for the width of RAD and sEMG were repeated, and also 1 hour and 24 hours later (follow up).

Randomization was carried out using computer-generated random numbers (simple randomization). The participants were randomly assigned to groups in a 1:1 ratio.

Intervention Type
Other

Primary outcome measure
The inter-recti distance is measured using a digital caliper at three sites: at the umbilicus and 4.5 cm above and below it at baseline, 10 min after the intervention, and 1 and 24 h later

Secondary outcome measures
The bioelectrical activity of the rectus abdominis muscle is measured using surface electromyography at baseline, 10 min after the intervention, and 1 and 24 h later

Overall study start date
21/12/2017

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. RAD >2 cm at least at one of three sites
2. Postnatal period >6 weeks and <12 months
3. BMI <30 kg/m²
4. Consent to participate in the trial

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
50 in each group

Key exclusion criteria
1. Multiple pregnancies
2. Cesarean delivery
3. Other surgeries in the abdominal area

Date of first enrolment
10/01/2018

Date of final enrolment
29/12/2021

Locations

Countries of recruitment
Poland

Study participating centre
Wroclaw Medical University
Physical Therapy Department
Grunwaldzka 2

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Poland
50-355

Sponsor information

Organisation
Wrocław Medical University

Sponsor details
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Sponsor type
University/education

Website
http://www.am.wroc.pl/en/

ROR
https://ror.org/01qpw1b93

Funder(s)

Funder type
Government

Funder Name
The Ministry of Science and Higher Education in Poland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Raw data (database taking into account the anonymity of patients), the data will become available from the end of the study, for 5 years. The research results will be passed on to other researchers in order to compare these results with the results of their own research.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article		28/10/2021	17/01/2023	Yes	No