Randomized, prospective, double-blind study to objectively demonstrate the performance and safety of the Rayocomp bioresonance device in patients with cervical spine disorder

Acronym/abbreviation of the study

R-HWS

URL of the study

No Entry

Brief summary in lay language

The study will assess the pain relief and improvement in the quality of life of patients with cervical spine disorder who have been treated with the Rayocomp bioresonance device. The study participants fill in questionnaires on quality of life, performance and neck pain (NDI). The study also assesses demographic and medical history data. In addition, the safety of the treatment will be investigated by recording adverse events during the study. During the study phase, 10 sessions of therapy with the Rayocomp bioresonance device or with a non-functional device (placebo) take place within up to 21 days. The evaluation of the data collected in this study is intended to increase knowledge of bioresonance therapy and to improve the treatment of patients with cervical spine disorder.

Brief summary in scientific language

This study is a randomized, prospective, double-blind study according to MPG §23b investigating treatment with the Rayocomp bioresonance device. The Rayocomp bioresonance device is a CE-certified medical device for alleviating the pain symptoms in patients with cervical spine disorder. The primary objective of the study is effectiveness as measured by the NDI; secondary objectives are safety, quality of life and VAS. A total of 52 patients shall be enrolled.

Organizational Data

DRKS-ID:
DRKS00017381

Recruitment Status:
Recruiting complete, study complete

Date of registration in DRKS:
2019-05-22

Last update in DRKS:
2020-05-14

Registration type:
Prospective

Health condition or problem studied

ICD10:
M54 - Dorsalgia

ICD10:
M53 - Other dorsopathies, not elsewhere classified

Healthy volunteers:
No Entry

Interventions, Observational Groups

Arm 1:
Treatment with the Rayocomp Bioresonance Device, 10 treatments over 21 days with acquisition of AE, demography, med. history at BL, determination of VAS, pain medication, 3 questionnaires - quality of life, performance, NID at BL and after last treatment, subjective assessment of therapeutic success after last treatment

Arm 2:
Treatment with non-functional Rayocomp Bioresonance Device (placebo), 10 treatments over 21 days with acquisition of AE, demography, med. history at BL, determination of VAS, pain medication, 3 questionnaires - quality of life, performance, NID at BL and after last treatment, subjective assessment of therapeutic success after last treatment

Endpoints

Primary outcome:
Neck pain, as measured by the Neck Disability Index (NDI), before and after treatment with the Rayocomp bioresonance device compared to placebo

Secondary outcome:
Safety, as measured by the incidence of adverse events

Quality of life measured on the SF-36 before and after treatment with the Rayocomp bioresonance device compared to the placebo

VAS before and after treatment with the Rayocomp bioresonance device compared to placebo

Study Design

Purpose:
Treatment

Study type:
Interventional

Assignment:
Parallel

Allocation:
Randomized controlled study

Mechanism of allocation concealment:
No Entry

Sequence generation:
No Entry

Control:
Placebo

Blinding:
Yes

Who is blinded:
Investigator/therapist, Patient/subject

Phase:
IV

Recruitment

Recruitment Status:
Recruiting complete, study complete

Reason if recruiting stopped or withdrawn:
No Entry

Recruitment Locations

Recruitment countries:
Germany

Number of study centers:
Monocenter study

Recruitment location(s):
Doctor's practice Melbeck

Recruitment period and number of participants

Planned study start date:
2019-05-23

Actual study start date:
2019-05-25

Planned study completion date:
No Entry

Actual Study Completion Date:
2019-12-12

Target Sample Size:
52

Final Sample Size:
54

Inclusion Criteria

Sex:
All

Minimum Age:
18 Years

Maximum Age:
no maximum age

Additional Inclusion Criteria:
1) Gender: male and female
2) Age: at least 18 years
3) At least moderate pain (≥ 5 on the VAS) in the cervical spine area
4) Neck disability index with at least medium restriction (score ≥ 15)
5) Patients must be able to understand the patient information
6) Patients must be willing and able to meet the requirements of the study
7) Signed ICF

Exclusion Criteria

1) Systemic or inflammatory musculoskeletal disease (e.g., muscular dystrophies, polymyositis)
2) Trauma with fractures and surgical treatment
3) Severe systemic disease with a life expectancy <6 months (e.g., advanced heart failure, malignancies)
4) Massive degenerative disease with marked restriction of motility (e.g., polyarthritis)
5) Pregnant or breastfeeding female patients without effective contraception
6) Patients who, due to mental illness, are unable to understand the study information, give their consent, or adhere to the study's guidelines
7) Patients who, in the opinion of the investigator, are not suitable for the study
8) Alcohol or drug abuse
9) patients incapable of giving consent
10) Persons who are in a dependency or employment relationship with the sponsor or investigator
11) Detained persons
12) Participation in another study

Addresses

Primary Sponsor

Rayonex Biomedical GmbH
Sauerland-Pyramiden 1
57368 Lennestadt
Germany

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Fax:
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Contact per E-Mail

URL:
http://www.rayonex.de

Investigator Sponsored/Initiated Trial (IST/IIT):
No

Contact for Scientific Queries

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Sources of Monetary or Material Support

Commercial (pharmaceutical industry, medical engineering industry, etc.)

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Ethics Committee

Address Ethics Committee

Ethikkommission bei der Ärztekammer Niedersachsen, Unterkommission zur Beurteilung medizinischer Forschung am Menschen
Karl-Wiechert-Allee 18-22
30625 Hannover
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URL:
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Vote of leading Ethics Committee

Date of ethics committee application:
2019-02-26

Ethics committee number:
11/2019

Vote of the Ethics Committee:
Approved

Date of the vote:
2019-02-28

Further identification numbers

Other WHO Primary Registry or Data Provider ID:
No Entry

UTN (Universal Trial Number):
No Entry

EudraCT Number:
No Entry

EUDAMED Number:
No Entry

IPD - Individual Participant Data

Do you plan to make participant-related data (IPD) available to other researchers in an anonymized form?:
No

IPD Sharing Plan:
No Entry

Study protocol and other study documents

Study protocols:
No Entry

Study abstract:
No Entry

Other study documents:
No Entry

Background literature:
No Entry

Related DRKS studies:
No Entry

Publication of study results

Planned publication:
No Entry

Publications/study results:
- R-HWS Zusammenfassung der Ergebnisse

Date of the first journal publication of results:
No Entry

DRKS entry published for the first time with results:
No Entry

Basic reporting

Basic Reporting / Results tables:
No Entry

Brief summary of results:
No Entry