Deep Sound Wave Therapy for the prevention of neuropathy in the treatment of colorectal and breast cancer with chemotherapy: a pilot / feasibility study '

Published: 17-05-2018
Last updated: 12-04-2024

The aim of this pilot is to get an impression of the feasibility and added value of administering deep sound waves to the body during (neo) adjuvant chemotherapy. In addition, we want to gain insight into whether or not complete completion of a...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46640

Source
ToetsingOnline

Brief title
DSWT study

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
neuropathy, neurotoxicity

Health condition

neuropathische aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Innovatie & wetenschap

Intervention

Keyword: Chemotherapy, DeepSoundWaveTherapy, Neuropathy, Pilotstudy

Outcome measures

Primary outcome

In order to assess whether neuropathy has developed after the last

chemotherapy, the primary endpoint was chosen 3 months after the last

treatment. The number of fully / dosed courses, prevention of neuropathy

(measured according to current guidelines in the department and measured with

the FACT / GOG-NTX-13 questionnaire), use of medication against neuropathy and

the experience of patients with DSWT (questionnaire Numerical Rating Scales /

open questions are registered

Secondary outcome

nvt

Study description

Background summary

The treatment of colorectal and breast carcinoma with (adjuvant) chemotherapy leads to neuropathy in more than 80% of the patients (even * 92% in colorectal carcinoma). These complaints are so serious that chemotherapy can not be completed according to the original schedule. For the above reasons, there is an urgent need for new innovations that can reduce or prevent side effects, so that patients have fewer complaints and complete dosing schedules. This

innovation is now possible in the form of Deep Sound Wave Therapy (DSWT). In this non-invasive treatment, patients sit in a chair where, during the course of the chemotherapy, treatment programs consisting of low-frequency sound waves (25-100 Hz) are administered to the body. Although the mechanism of action is still insufficiently known, results from a first (not yet published) study in the US suggest that this treatment has an added value in the reduction of symptoms due to neuropathy.

Study objective

The aim of this pilot is to get an impression of the feasibility and added value of administering deep sound waves to the body during (neo) adjuvant chemotherapy. In addition, we want to gain insight into whether or not complete completion of a chemotherapy, reducing the incidence of neuropathies and the use of medication against neuropathy, and the experience of patients with this new treatment. In addition, these studies are collected that can be used to calculate a sample size for future studies.

Study design

A non-invasive pilot / feasibility study in which the results are compared with two historical cohorts

Intervention

During the CapOX / AC-P treatment, test subjects take place on the DSWT chair instead of on a regular chair and receive specific DSWT treatments in that chair.

Study burden and risks

DSWT is applied during the regular administration of the chemotherapy (including other medication). In addition, participants have to go to the hospital for an extra 1x for the DSWT treatment (frequency + duration). If DSWT has an added value then patients can complete the chemotherapy according to the original schedule, they have fewer complaints of neuropathy and the use of medication for neuropathy decreases. Until now there are no negative effects on the chemotherapy treatment known.

Contacts

Public
Isala Klinieken

Dr. Deenweg 1-11
8025Bp, Zwolle 8025BP
NL
Scientific
Isala Klinieken

Dr. Deenweg 1-11
8025Bp, Zwolle 8025BP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

subjects who will start adjuvant chemotherapy in the form of CapOx or Paclitaxel.
subjects in the age of >18 year

Exclusion criteria

subjects with a pacemaker
subjects with a weight greater than 140 kg.
subjects previously treated with neurotoxic medication
Patients with active rheumatoid arthritis.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Sonus DSWT
Registration:	No

Ethics review

Approved WMO

Date:	17-05-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL64994.075.18