Dupuytren*s disease Evaluation of Preventative or Adjuvant Radiation Therapy

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Primary objective: To show a meaningful reduction in progression of DD with the application of radiotherapy both in the early stages as well as following local treatment in the later stages.Secondary objectives: 1. Report physician graded toxicity...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON54267

Source
ToetsingOnline

Brief title
DEPART-trial

Condition

- Connective tissue disorders (excl congenital)

Synonym
Dupuytren's disease, Viking disease

Research involving
Human

Sponsors and support

Primary sponsor: GenesisCare Cancer Care Research Pty Ltd
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adjuvant radiotherapy, Dupuytren's disease, Preventive radiotherapy, Toxicity

Outcome measures

Primary outcome

To show a meaningful reduction in progression of DD with the application of radiotherapy both in the early stages as well as following local treatment in the later stages.

Primary Endpoint is Disease Progression, defined as:

- Prevention Group: Measurement of 20 degrees, or greater, PED in joint(s) of an affected hand OR instigation of salvage SF or NA to the affected hand or
- Adjuvant Group: Deterioration greater than 20 degrees PED in any joint(s) of any of the affected digit(s) from post-intervention baseline in the presence of a palpable cord OR instigation of salvage SF or NA to any of the affected digit(s).

Secondary outcome

• Acute toxicity

• Patient reported quality of life

• Late toxicity

Study description

Background summary

Dupuytren*s Disease (DD) is a genetic disorder of the myofibroblasts characterised by the deposition of collagen within the fascia of the hands

which can eventually lead to the development of flexion contractures. No intervention has been definitively shown to reduce the likelihood of disease progression.Low dose radiotherapy has a long history of being deployed prior to development of significant contractures with the intention of preventing disease progression.Most of the data suggests that the risks of radiotherapy are low, and that only a minority of patients who receive such treatment will progress with long term follow-up. Some influental recent reviews however conclude that the evidence base to justify radiotherapy as a standard treatment option is poor. Conversely, more advanced DD has a range of interventions available with the aim of reducing flexion contractures and improving dexterity. Three main approaches are used:
1. Surgical Fasciectomy (SF)
2. Needle Aponeurotomy (NA)
A comprehensive understanding of the toxicities of radiotherapy in the management of DD has not been well reported due to firstly the preponderance of single institution, largely retrospectively acquired data, but also that much of this is physician assessed rather than patient reported. As such, an important part of this study would be to prospectively collect both physician and patient reported outcomes (PROs).

Study objective

Primary objective:
To show a meaningful reduction in progression of DD with the application of radiotherapy both in the early stages as well as following local treatment in the later stages.

Secondary objectives:
1. Report physician graded toxicity for radiotherapy.
2. Compare patient reported pain and functional outcomes via validated tools for radiotherapy versus observation between arms at 1, 3, 5, 7 and 9 years, as well as within arms between baseline and 9 years, or at progression, whichever arrives first.

Study design

An international, multicenter, randomized controlled clinical phase III trial - Observation (standard of care) v Radiotherapy (experimental arm)

Intervention

30Gy in 10 fractions of split course Radiotherapy compared with Observation in both prevention and adjuvant settings. The time between the two courses is about 10 weeks.

Study burden and risks

Study load:
Patients randomized to receive radiotherapy treatment must come to the hospital daily for 2 weeks for radiation treatment. In addition, the inspections in the context of the research are more frequent than is currently applied in clinical practice.

Risk:
Very low risk of radiation-induced skin cancer (estimated at <0.1% for life)

Justification:
With this study, the effectiveness of radiotherapy as a treatment method for Dupuytren's disease can be proven. In case of a positive effect of the radiotherapy treatment, an advantage for the patient, treated with radiotherapy, may be that there is an improvement of the complaints (including pain, irritation / itching, curvature, size of the nodules and / or strands) as a result. of Dupuytren's disease.
The chance of developing a radiation-induced malignancy is very low.

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

Prevention cohort
• Evidence of nodules and/or cords in the affected hand consistent with DD
• History of progressive DD over previous 6 months
• No previous radiotherapy to the affected hand
• No history of radiation sensitivity diseases (eg Scleroderma, Ataxia Telangiectasia, Li Fraumeni)
• No previous SF, NA or CI in the affected hand
• Absence of flexion contractures: Passive extension deficit (PED) must be less than, or equal to, 10 degrees (<=10°) in any joints of the affected hand.
• Age>30
• Patient Consent

Adjuvant cohort
• Local treatment with Needle Aponeurotomy (NA) of flexion contracture(s) performed within 6-12 weeks prior to post-intervention baseline measurements
• Age>30
• No previous radiotherapy to the affected hand
• No history of radiation sensitivity diseases (eg Scleroderma, Ataxia Telangiectasia, Li Fraumeni)
• Lack of major acute complications due to surgical intervention and <=20 degrees PED in each joint of treated ray
• Able to commence radiotherapy treatment within 12 weeks of local treatment with Needle Aponeurotomy (NA).
• Patient consent

Exclusion criteria

Prevention cohort
• No evidence of nodules and/or cords in the affected hand consistent with DD
• No history of progressive DD over previous 6 months
• Previous radiotherapy to the affected hand
• History of radiation sensitivity diseases (eg Scleroderma, Ataxia Telangiectasia, Li Fraumeni)
• Previous SF, NA or CI in the affected hand
• Prescence of flexion contractures: Passive flexion contracture greater than 10 degrees (>10°) in all joints of the affected hand.

• Age <= 30
• No patient Consent

Adjuvant cohorts
• Local treatment with Needle Aponeurotomy (NA) of flexion contracture(s) is not performed within 6-12 weeks prior to post-intervention baseline measurements
• Age<=30
• Previous radiotherapy to the affected hand
• History of radiation sensitivity diseases (eg Scleroderma, Ataxia Telangiectasia, Li Fraumeni)
• Major acute complications due to surgical intervention and >20 degrees PED in each joint of treated ray
• Not able to commence radiotherapy treatment within 12 weeks of local treatment with Needle Aponeurotomy (NA).
• No patient consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-08-2023
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2023

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-03-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-12-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	ACTRN12618000951257p
CCMO	NL77182.042.21