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Laser therapy in treatment of Trigger Finger and De Quervains

Submission date	Recruitment status	[X] Prospectively registered
01/04/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/04/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/01/2017	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to establish an alternative treatment for patients with two particular forms of Tenosynovitis; Trigger Finger disease or De Quervains. These separate pathologies constitute the majority of referrals from our local GP practices to our Musculoskeletal Clinical Assessment, Triage and Therapy Service (MCATTS) at Guy's & St Thomas Hospitals.

A tendon is a strong tissue that attaches a muscle to a bone. In these cases the tendons come from muscles in the forearm and attach to the bones of the thumb or fingers, by passing through the palm. The muscle pulling on these tendons bend the fingers towards the palm, or straighten the thumbs. Tendons are encased within a tunnel of tissue called a tendon sheath that covers and protects the tendons, whilst allowing them to slide in and out without any friction. When the sheath becomes inflamed this is termed tenosynovitis.

In trigger finger disease the tendon cannot easily slide back in due to the swelling of the tendon or the sheath. The finger can become locked unless you straightened forcefully. In De Quevains disease, the tendons that straighten the thumb are involved due to a tenosynovitis. The typical symptom is pain over your wrist at the base of your thumb that is made worse by activity and eased by rest.

Laser therapy has shown clinical success in a wide variety of musculoskeletal and wound healing scenarios. This study aims to quantify the effect of laser therapy on the treatment of trigger finger disease in diabetic and non-diabetic groups and De Quervains Tenosynovitis.

The study shall quantify both the effectiveness of laser by reducing symptoms, finger-locking, and improving function. We also aim to establish the duration of treatment required for both in terms of hospital visits, and days from the initial consultation.

Who can participate?

Any patient 18 years of age or older with full mental capacity and no active cancer

What does the study involve?

There are 3 groups in this study:

1. Trigger finger in non-diabetics
2. Trigger finger in diabetics
3. Patients with De Quervains

We will expect to recruit about 30 patients in each group and randomly assign half into receiving

laser therapy (receiving 2 sessions a week for 6 weeks), and half to splinting (for 6 weeks).
If patients have not improved in either group we will then proceed to our standard level of care.

What are the possible benefits and risks of participating?
Currently each trigger finger disease and De Quervains are managed by splinting, proceeding to steroid injections and then ultimately surgery. Steroid injections can be very painful, and can increase the risk of infection and tendon rupture. In diabetics it has also been shown to affect blood sugar levels for more than 5 days, which can be problematic in insulin controlled diabetics. Surgery carries further risks of pain, infection, bleeding and scarring.
K-laser is a non-invasive alternative that avoids all of these potential risks. There has not been a single reported case of any form of complication associated with high intensity laser therapy. There are however many examples of where this novel treatment modality can enhance recovery of different forms of tendonitis and chronic inflammatory changes. The risk profile associated with this study is therefore negligible based on published evidence.

Where is the study run from?
The Hand therapy department, Third Floor, Lambeth Wing, St Thomas Hospital

When is the study starting and how long is it expected to run for?
The study is expected to run from June 2013-June 2014

Who is funding the study?
Guys & St Thomas NHS Trust

Who is the main contact?
Mr Mohammed Tahir
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Contact information

Type(s)
Scientific

Contact name
Mr Mohammed Tahir

Contact details
Guy's & St Thomas' NHS Foundation Trust
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Laser therapy in treatment of Trigger Finger and De Quervains: a randomised control trial

Study objectives
High intensity laser therapy is effective in treating inflammatory hand conditions including trigger finger and de quervains tenosynovitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Trigger finger disease, De Quervains tenosynovitis

Interventions
There are 3 groups in this study:
1. Trigger finger in non-diabetics:
1.1. 15 patients treated with Laser therapy
1.2. 15 patients treated with splinting
2. Trigger finger in diabetics:
2.1. 15 patients treated with Laser therapy
2.2. 15 patients treated with splinting
3. Patients with De Quervains:
3.1.15 patients treated with Laser therapy
3.2. 15 patients treated with splinting

All K-laser patients are treated twice weekly for 6 weeks, at a fixed dosage of 6-8 Joules/cm2 and average power density of 1-2 Watts/cm2 with the treatment time to be adjusted based on the treatment size of the individual patient.

The Laser Treatment Parameters:

Wavelengths employed:
1. 660 nm (average power of 50 mW)
2. 800 nm (average power of 5 W)
3. 905 nm (average power of 5 W)
4. 970 nm (average power of 5 W)

Frequencies employed:
Each protocol consists of 10 sub-phases each with a different pulse frequency:
Phase 1: Continuous Wave (CW frequency = 0 Hz)
Phase 2: 2 Hz (Duty Cycle = 50%)
Phase 2: 10 Hz (Duty Cycle = 50%)
Phase 3: 50 Hz (Duty Cycle = 50%)
Phase 4: 100 Hz (Duty Cycle = 50%)
Phase 5: 500 Hz (Duty Cycle = 50%)
Phase 6: 2500 Hz (Duty Cycle = 50%)
Phase 7: 7500 Hz (Duty Cycle = 50%)
Phase 8: 15,000 Hz (Duty Cycle = 50%)
Phase 9: 20,000 Hz (Duty Cycle = 50%)
Phase 10: Continuous Wave (CW frequency = 0 Hz)

Treatment time:
3 minutes (+/- 10% for patient hand/arm size variation)

Power:
In CW mode, Peak Power = Average Power = 5 Watts
In Hz mode, Peak Power = 10 Watts, Average Power = 5 Watts

We will then measure outcome scores as defined by:

Functional:
Group 1:
1. Presence of finger locking or not
2. Clinical Tenderness at A1 or not

Group 2:
1. Presence of finger locking or not
2. Clinical Tenderness at A1 or not

Group 3:
Objective:
1. Lateral pinch strength
2. Tripod pinch strength
Subjective: better / same / worse

Symptom:
Group 1:
1. Pain according to Visual Analogue Score
2. Functional is the finger better, the same, or worse

Group 2:
1. Pain according to Visual Analogue Score
2. Functional is the finger better, the same, or worse.

Group 3:
1. Pain on Finklestein test Yes /no.
2. Pain on resisted MCPJ1 Extension Yes /no.
3. Pain according to Visual Analogue Score

If patients have not improved in either group we will then proceed to our standard level of care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Does high intensity laser therapy reduce symptoms of finger locking and pain in trigger finger disease (a condition where finger tendons can inflammed and become locked in a flexed/bent position facing the palm), and does it reduce pain and improve strength in de quervains disease (inflammed tendons of the thumb).

Key secondary outcome(s))
1. The number of laser treatments sufficient to treat trigger finger disease and de quervains
2. The number of complications prevented by treating patients with laser therapy versus splinting
3. The cost effectiveness of treating patients with laser therapy versus splinting

Completion date
01/06/2014

Eligibility

Key inclusion criteria
We have 3 separate cohorts in our study:

1. Cohort 1 Trigger Finger - all adults, either sex, aged 18 and over with single or multiple digit trigger finger disease.

2. Cohort 2 Trigger finger in diabetics with bilateral disease- all adults, either sex, aged 18 and over with symmetrical bilateral trigger finger(s) and a diagnosis of diabetes mellitus.

3. Cohort 3 De Quervains - all adults, either sex, aged 18 and over with De Quervains tenosynovitis.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
Cohort 1:
1. Under 18 years
2. Those with a diagnosis of diabetes mellitus
3. All patients with a diagnosis of any form of cancer
4. Any patient >65 years old
5. With minimental state examination (MMSE) <21

Cohort 2:
1. Under 18 years
2. All patients with a diagnosis of any form of cancer
3. Any patient >65 years old
4. With MMSE <21

Cohort 3:
1. Under 18 years
2. All patients with a diagnosis of any form of cancer
3. Any patient >65 years old
3. With MMSE <21

Date of first enrolment
01/06/2013

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's & St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's & St Thomas' NHS Foundation Trust (UK)

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's & St Thomas' NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes