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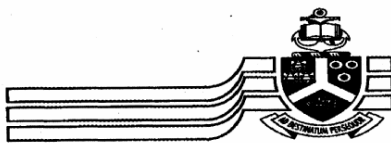
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APPENDICES



APPENDIX 1: STUDENT PROTOCOL AND THE ETHICAL COMMITTEE



University of Pretoria

Faculty of Health Sciences Research Ethics Committee

University of Pretoria

Tel (012) 339 8619

Fax (012) 339 8587

E Mail dbehari@med.up.ac.za

Soutpansberg Road Private Bag x 385

MRC-Building Pretoria

Level 2 0001

Room 19

Date: 31/07/2002

Number : **S166/ 2002**

Title : The effects of manual fascia release on the symptoms of chronic posterior compartment syndrome

Investigator: Estelle Erasmus, Department of Physiotherapy, University of Pretoria

Sponsor : None

This Student Protocol has been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 30/07/2002 and found to be acceptable.

Prof P Carstens	BLC LLB LLD (Pret) Faculty of Law
Dr J.E.Dafel	(female) MBChB: Hospital Superintendent
Prof A.P.du Toit	BA; DiplTheo; BA (Hons); MA; DPhil: Philosopher
Prof S.V. Grey	(female) BSc (Hons); MSc; DSc: Deputy Dean
Dr V.O.L. Karusseit	MBChB; MFGP (SA); M.Med (Chir); FCS (SA): Surgeon
Dr S.Khan	(female) MB.BCh.; Med. Adviser (Gauteng Dept.of Health)
Prof M Kruger	(female) MB.ChB.(Pret); Mmed.Paed.(Pret); PhDd. (Leuven)
Miss B Mullins	(female) BscHons; Teachers Diploma;
Snr Sr J. Phatoli	(female) BCur (Et.Al) Senior Nursing-Sister
Prof H.W. Pretorius	MBChB; M.Med (Psych) MD: Psychiatrist
Prof P. Rheeder	MBChB; M.Med (Int); LKI (SA); MSc (CLIN.EPI): Specialist Physician
Dr C F Slabber	BSc (Med)MB BCh, FCP (SA) Acting Head; Dept Medical Oncology
Prof J.R. Snyman	MBChB, M.Pharm.Med: MD: Pharmacologist
Prof De K.Sommers	BChB; HDD; MBChB; MD: Pharmacologist
Dr R Sommers	(female) MBChB; M.Med (Int); MPhar.Med;
Dr TJP Swart	BChD, MSc (Odont), MChD (Oral Path) Senior Specialist; Oral Pathology

Student Ethics Sub-Committee

Mrs E Ahrens	(female)B.Cur;
Prof S Meij	(female)BSc(Hons);MSc
Prof P. Rheeder	MBChB;M.Med(Int);LKI(SA);MSc (CLIN.EPI): Specialist Physician
Dr R Sommers	SECRETARIAT (female)MBChB; M.Med (Int); MPharMed;
Dr C van der Westhuizen	(female) D.Cur; M.Ed.
Mrs N Lizamore	(female) BSc(stell), BSc (Hons) (Pret),MSc (Pret) Dept. Anatomy

PROF J R SNYMAN

MBChB, M.Pharm.Med MD: Pharmacologist
CHAIRPERSON of the Faculty of Health Sciences Research
Main Ethics Committee - University of Pretoria

PROF P. RHEEDER

MBChB, M.Med (Int), LKI (SA); MSc (CLIN.EPI): Specialist Physician
CHAIRPERSON of the Faculty of Health Sciences Research
Students Ethics Committee – University of Pretoria



Universiteit van Pretoria

Pretoria 0002 Republiek van Suid Afrika
[Http://www.up.ac.za](http://www.up.ac.za)

FACULTY OF HUMANITIES

Dept Biokinetics, Sport & Leisure Sciences

Tel: 012-420-6040 Fax: 012-420-6099

www.bsl.up.ac.za

APPENDIX 2: PATIENT INFORMED CONSENT

Patient information leaflet and informed consent

(Each patient must receive, read and understand this document before the start of the study)

Trial Title

Clinical trial no: S166/ 2002

Multiple single case studies in the form of a clinical trial in patients with chronic posterior compartment syndrome to investigate the effect of manual fascia release techniques on the symptoms.

Introduction

You are invited to volunteer for a research study. The information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator (Estelle) for clarification. You should not agree to take part unless you are completely satisfied with the procedures involved.



What is the purpose of this trial?

You have a running injury called posterior compartment syndrome, which causes an increase in pressure inside a compartment of the calf muscles. This increase in pressure inside the compartment commences after a certain period of time while running and causes pain and stiffness. A new manual technique is currently being developed in order to release the fascia (a type of soft tissue) involved in the dysfunctional compartment. It is hypothesized that the dysfunctional fascia is the cause of the symptoms of chronic posterior compartment syndrome.

Patients participating will all be runners between the ages of 18 and 50 years, male or female who takes part in road races of distances of ten kilometres or more.

What is the duration of this trial?

Since the study will have an exploratory component it is very difficult to predetermine the duration of the study. Whilst new information is gained, it is likely that the study will continue. It is expected of the participants to commit for a time period of at least six months.

During the intervention, manual fascial release techniques (which can be compared to a soft tissue stretch) will be used. It will be expected of you to continue running while taking part in the study and you will receive home stretches to do on a daily basis.

Has the trial received ethical approval?

This clinical trial protocol was submitted to the Research Ethics Committee and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2000), which deals with the recommendations guiding doctors in biomedical research involving human subjects. A copy of which might be obtained from the investigator (Estelle) should you wish to review it.

What are my rights as a participant in this trial?

Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating the reason. Your withdrawal will not affect your access to other medical care. The investigator (Estelle) retains the right to withdraw



you from the study if it is considered to be in your interest. If it is detected that you did not give an accurate history or did not follow the guidelines of the trial and the regulations of the trial facility, you may be withdrawn from the trial at any time.

Is alternative treatment available?

Alternative treatment in the form of surgical release of the fascia is often used to treat posterior compartment syndromes. If you decide not to take part in this study you might select this option and ask to be referred to an orthopaedic surgeon.

May any of this trial procedures result in discomfort or inconvenience?

The only inconvenience experienced might be the time you need to sacrifice to come for the interventions. It will be expected of you to carry on running; so no sacrifices are made in this regard. Manual fascia release is not a painful technique. It is a slow, hold type of release that might feel similar to a stretch sensation.

What are the risks involved in this trial?

There are no risks involved. With the involvement of any serious pathology, you will be excluded from this trial.

Are there any warnings or restrictions concerning my participation in this trial?

No

Discontinuation of trial treatment

You may at any point in time decide to discontinue.

Insurance and financial arrangements

Neither you nor your medical scheme will be expected to pay for any of the visits to the investigator (Estelle) if you are included in the trial with the diagnosis of chronic posterior compartment syndrome for the duration of the trial. If you require to be treated for another condition which is not related, it can be expected of you or your medical aid to carry the costs thereof.

You will not be paid to participate in the trial.



Source of additional information

For the duration of the trial you will be under the care of Estelle Erasmus. If at any time between your visits you feel that any of your symptoms are causing you problems, or you have any questions during the trial, please do not hesitate to contact Estelle Erasmus at 082-779-2582 or 991-4499.

Confidentiality

All information obtained during the course of this trial is strictly confidential. Data which may be reported in scientific journals will not include any information which might identify you as a person in this trial.

In connection with this trial, it might be important for domestic and foreign regulatory health authorities and the Research Ethics Committee of the South African Medical Association, as well as your personal doctor, to be able to review your medical records pertaining to this trial. Therefore you hereby authorize your investigator (Estelle) to release your medical records to domestic or foreign regulatory health authorities, the Medicines Control Council and the Research Ethics Committee of the South African Medical Association. You understand that these records will be used by them only in connection with carrying out their obligations relating to this clinical trial.

Any information uncovered regarding your test results or health as a result of your participation in this trial will be held in strict confidence. You will be informed of any findings of importance to your health or continued participation in this trial but this information will not be disclosed to any third party in addition to the ones mentioned above without written permission. The only exception to this rule will be in cases in which a law exists compelling us to report individuals infected with communicable diseases. In this case, you will be informed of our intent to disclose such information to the authorized state agency.

Informed consent

I hereby confirm that I have been informed by the investigator, Estelle Erasmus, about the nature, conduct, benefits and risks of the trial. I have also received, read and



understood the above written information (patient information leaflet and informed consent) regarding this trial.

I am aware that the results of this trial, including personal details regarding my sex, age, date of birth, initial and diagnosis will be anonymously processed into a trial report.

I may, at any time, without prejudice, withdraw my consent and participation in the trial. I have had sufficient opportunities to ask questions and (out of my own free will) declare myself prepared to participate in the trial.

Patient's name: _____ (please print)

Patient's _____ signature:
_____ Date _____

Investigator's name: _____ (please print)

Investigator's signature: _____
Date _____

I,.....herewith confirm that the above patient has been fully informed about the nature, conduct and risks of the above trial.

Witness's name : _____ (please print)

Witness's signature: _____ Date: _____



APPENDIX 3: E-MAIL FOR THE RECRUITMENT OF SUBJECTS

Dear Fellow Runner

PhD study on Sport Injuries:

This is a call for all those runners who have been or who are currently suffering with symptoms of chronic posterior compartment to participate in a research study!

What is chronic compartment syndrome?

Chronic compartment syndrome is a pathological condition of muscle, characterized by increased pressure within an anatomically confined muscle compartment. This increased pressure interferes with the circulation and function of the muscle and neurovascular components of the compartment. When this occurs in the posterior compartment of the lower leg, it is called a posterior compartment syndrome. A condition is usually defined as chronic when it has been present for a period of at least three months.

Symptoms of chronic posterior compartment

The main symptom is activity related pain in the Calves. Both Calves are often affected. The pain increases with exercise and decreases with rest. The area over the calf muscles often feel and appear swollen after exercise. Stretching of the calf muscles often elicit pain. Occasionally there might be a sensation of pins and needles or numbness in the foot. The calf muscles feel tense and tender. Sometimes the pain sensation is also describes as a cramp like sensation.

What does participation in the study entail?

What are the advantages of participation in the study?

- You might become pain free and will be able to run PB's again (providing you train of course!).
- Free physiotherapy treatment once a week for a couple of weeks specifically for this injury.



-Professional advice with regard to training programmes, correct running shoes, stretches and other information on the injury.

What are the disadvantages of participation in the study?

None! (You might not have an excuse for running poorly anymore)

You qualify for the study if you:

- are 18 – 50 years of age
- actively participating in road races with a distance of 10 kilometres or more
- are willing to train throughout the intervention period
- have been diagnosed with chronic posterior compartment syndrome or have had symptoms of chronic posterior compartment in one or both legs for a period of more than three months.
- pass an interview and a process of differentiation by the researcher to ensure that the injury is definitely a chronic compartment syndrome.

For further information, please contact Estelle Erasmus at 082-779-2582.

Cheers, see you on the road!