Informed Consent Form

Date: 24/06/2025

Title of the Research Project:

Sequelae of upper limb burns, functional contractures, and pathological scars: a randomized clinical trial of fat grafting versus corticosteroid injection

Principal Investigator:

Alfredo Gragnani Filho

Research Team:

Alfredo Gragnani Filho and Marcelo Oliveira Mourão Junior

Location:

Hospital São Paulo – Discipline of Plastic Surgery – Burn Treatment Unit (UTQ)

Invitation to Participate

You are invited to voluntarily participate in the research project described above voluntarily. You are being asked because you are receiving care at the Burn Treatment Unit (UTQ) of the Plastic Surgery Discipline at Hospital São Paulo, affiliated with the Escola Paulista de Medicina – Universidade Federal de São Paulo (UNIFESP). Your participation is important, but you should not feel obligated.

All information collected in this study will be confidential. Only the research team will have access to your identity, which will be kept anonymous. The data will be used solely for research purposes. At any time, before, during, or after the study, you may ask for further clarification, refuse to participate, or withdraw without any penalty or consequence.

If you have questions, you may contact:

Dr. Alfredo Gragnani Filho – Tel: +55 11 99658-4632 – Email: alfredo.gragnani@unifesp.br

Dr. Marcelo Oliveira Mourão Junior – Tel: +55 11 99356-7651 – Email: marcelo.mourao@unifesp.br

Participant Rights

For more information about your rights as a research participant, you may access the booklet developed by the Brazilian National Research Ethics Commission (CONEP).

This study has been reviewed and approved by a Research Ethics Committee (REC), which is responsible for overseeing the ethical aspects of human research. If you have questions about your rights or are dissatisfied with how the study is being conducted, you may contact:

REC–UNIFESP

Rua Sena Madureira, 1500 – 2nd floor – Vila Clementino – São Paulo, SP – Brazil – ZIP: 04021-001

Email: cep@unifesp.br – Tel: +55 11 3385-4343, extensions 8699 / 8557

Office hours: Monday to Friday, 8:00 AM to 1:00 PM

Study Information

Justification

Burn injuries represent a major public health issue, often leading to physical and psychological sequelae, work absence, and reduced quality of life. When upper limbs (hands, forearms, elbows, arms, shoulders) are affected, and complications such as contractures or pathological scars occur, the impact can be especially severe. This study aims to investigate and compare two treatment strategies:

- **Control Group:** corticosteroid injections (triacinolone)
- **Experimental Group:** autologous fat grafting (lipofilling)

Participants will be randomly assigned to one of the two groups and followed for 6 months. If the fat grafting proves more effective, this option will be offered to the control group participants at no cost.

Study Objectives

To compare fat grafting (experimental group) versus corticosteroid injection (control group) in the treatment of post-burn sequelae of the upper limbs.

Target Population

Burn victims with functional sequelae and/or pathological scars on the upper limbs.

Procedures

Volunteers will be randomly assigned to one of two groups:

- **Experimental Group:** autologous fat grafting
- **Control Group:** corticosteroid injection

Participants will remain in their assigned group throughout the 6-month evaluation period.

Risks of Participation

Fat Grafting Group:

As a surgical procedure, risks may include bleeding, seroma, infection, need for reoperation, or wound dehiscence. All necessary precautions will be taken before, during, and after the procedure to minimize risks.

Corticosteroid Group:

Risks may include pain at the injection site, allergic reactions, infection, excessive skin retraction or discoloration. Standard safety measures will be followed to ensure a safe procedure.

In the event of any adverse event, medical care and follow-up will be provided free of charge. If a causal relationship with the study is established, participants may be entitled to legal compensation.

If any clinical or emotional condition is identified during the study (e.g., emotional distress), the research team will offer appropriate guidance and referrals to public healthcare services.

All transportation and food expenses related to participation will be covered by the research team. There will be no costs to the participant.

Benefits of Participation

Fat grafting has shown positive effects on scar quality, skin elasticity, range of motion, and reduction of pain and itching. Participants will receive treatment at no cost and continuous follow-up by the research team. Indirect benefits include advancing scientific knowledge in burn care.

Privacy and Confidentiality

All personal data will be protected. No identifying information will be published. Study results may be shared or published, but always anonymously.

Access to Results

Participants may request access to partial or final study results.

Costs and Compensation

There are no costs or financial compensation involved. All study-related expenses (e.g., transport, food) will be covered by the research budget.

Consent Statement

I, the undersigned, voluntarily agree to participate in this research study. I have been fully informed about the study objectives, procedures, risks, and potential benefits. I understand that I can withdraw at any time without penalty. I authorize the use of my data for research purposes under confidentiality. I received a copy of this signed and initialed consent form.

Participant Name: _____

Signature: _____

Location and Date: _____

Declaration of the Investigator

I, the undersigned, declare that I will ensure the confidentiality and secure storage of all participant data. I confirm that I have explained the study details and answered all participant questions.

Principal Investigator: Alfredo Gragnani Filho

Signature: _____ **Date:** _____

Co-investigator/Witness: Marcelo Oliveira Mourão Junior

Signature: _____ **Date:** _____
