

Skin biopsy for research in genetic metabolic diseases

Published: 14-01-2008

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To obtain skin biopsies of healthy volunteers for scientific research.

Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON30876

Source

ToetsingOnline

Brief title

Skin biopsy for research in genetic metabolic diseases

Condition

- Neurological disorders congenital

Synonym

Niet van toepassing

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: genetic metabolic disease, skin biopsy

Outcome measures

Primary outcome

Not applicable.

Secondary outcome

Not applicable.

Study description

Background summary

Fibroblasts are an excellent model system for the study of metabolic disease. Besides patient cell lines, fibroblasts from healthy volunteers are also necessary to obtain reference values for the measured parameters. Cells can be cultured for only a few months before they lose the ability to divide (non-immortalized cells). Therefore a fresh supply of biopsies is necessary from time to time. Healthy individuals rarely undergo skin biopsies, and the consequence is that these cells are relatively scarce. Using leftover tissue (from surgery or cadavers) is not a feasible option, since these cells are often of poor quality (not immediately preserved in culture medium, contaminated with micro-organisms). The goal of this project is to obtain skin biopsies from healthy volunteers for the scientific study of metabolic disease.

Study objective

To obtain skin biopsies of healthy volunteers for scientific research.

Study design

Healthy volunteers undergo a skin biopsy in an outpatient clinic setting.

Study burden and risks

Participants undergo one skin biopsy, which is sometimes considered painful. There is a minimal risk of wound infection. A scar may be visible after wound healing.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Healthy male or female over 18 years of age

Exclusion criteria

Disorders of the coagulation system making a skin biopsy unsafe

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2007

Enrollment: 10

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

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

CCMO

ID

NL18194.018.07