

Application no:	Arrived:	
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Application for Scandiatransplant Research Grant

1. Study title

Donor-derived cell-free DNA (dd-cfDNA) for monitoring and early, non-invasive detection of allograft rejection in heart transplant patients

2. Aim of the study and a short description.

A short summary, including aim, methods, implementation and scientific value of the study.

Max 300 words.

Introduction: Allograft rejection is a critical yet treatable condition. However, early diagnosis is essential to improve long-term outcome and prognosis. Rejection is often detected when symptoms of allograft failure emerge at which irreversible damage to the allograft might have occurred. Dd-cfDNA has been suggested as a marker of early allograft rejection after heart transplantation.

Aim: This research project aims to evaluate dd-cfDNA as a marker of early allograft rejection in the first year after heart transplantation and to implement the dd-cfDNA analysis in the monitoring of heart transplant patients.

Methods: The project is planned and executed in three partially, overlapping phases conducted over a project period of 3 years. Phases include:

Phase 1: Analytical setup and laboratory validation (6 months) in which the dd-cfDNA analysis will be established at Department of Clinical Immunology, Aarhus University Hospital, and validated to ensure reliability and reproducibility important to the later implementation to clinical care.

Phase 2: Clinical test and validation (3 years) in which a clinical observational cohort, comprising 67 heart transplant patients is established. Data relevant to the study aim, i.e., clinical, immunological and pathological data are obtained on the days of myocardial biopsies (10-16 times in one year). Protocolized dd-cfDNA measurements are performed 4 times during the study period and if allograft rejection is suspected.

Phase 3: Clinical implementation (6 months) in which the additional organisational foundation for implementation is established. The project is designed and conducted in a real-life setting to ensure an easy, quick and safe implementation of dd-cfDNA to clinical practice.

Scientific value: The implementation of dd-cfDNA is expected to create value by possibly reducing the number of myocardial biopsies, strengthening diagnostic capabilities, and enabling closer monitoring, supporting clinical care of heart transplant patients and to prolong allograft functionality.

Word count: 294

3. Principal investigator

A person who is responsible for communication with Scandiatransplant

Name: Marie Skougaard

Title: MD, PhD

Job: 3rd year specialist registrar in clinical immunology

Hospital/ department: Department of Clinical Immunology, Aarhus University Hospital

Address/telephone/fax: Palle Juul-Jensens Boulevard 99, 8200 Aarhus N, Denmark,
Telephone: (+45) 24639609

E-mail: maisou@rm.dk

4. Co-investigators:

Name: Pernille Koefoed-Nielsen	Hospital: Department of Clinical Immunology, Aarhus University Hospital, Aarhus, Denmark Title: Senior consultant, MD, PhD, EFI-co-director E-mail: pernkoef@rm.dk
Name: Hans Eiskjær	Hospital: Department of Cardiology, Aarhus University Hospital, Aarhus, Denmark Title: Professor, MD, DMSc E-mail: hanseisk@rm.dk
Name: Kasper Rossing	Hospital: Department of Cardiology, Rigshospitalet, Copenhagen, Denmark Title: MD, DMSc E-mail: kasper.rossing@regionh.dk
Name: Kaspar Broch	Hospital: Department of Cardiology, Oslo University Hospital Rikshospitalet, Oslo, Norway. Title: MD, PhD E-mail: sbbrok@ous-hf.no

5. Accounting management

Person/company: Heidi Tobiasen, Department of Clinical Immunology, Aarhus University Hospital

Address: Palle Juul-Jensens Boulevard 99, 8200 Aarhus N, Denmark

Telephone/Fax number: 78455097

E-mail: heitob@rm.dk

6. Budget plan for the project period

Please state the amount in €

Cost detail	Scandiatransplant funding	Other funding	Total cost
Salaries (and related expences)			
Name: Unnamed lab tech, AUH	€0	€36,187.00	€36,187.00
Name: Unnamed project nurse, AUH	€18,094.00	€0	€18,094.00
Name: Unnamed project nurse, CPH	€18,094.00	€0	€18,094.00
Name: Unnamed project nurse, Oslo	€18,094.00	€0	€18,094.00
Laboratory expenses	€1,341.00	€103,347.00	€104,688.00
Administrative costs	€1,669.00	€0	€1,669.00
Travel expenses	€0	€0	€0
Other			
Total	€57,292.00	€139,534.00	€196,826.00

A detailed budget is included in the project description

7. Signatures

The principal investigator and all other co-proposers shall sign this.

Signature of principal investigator

Place and date: Aarhus, 31.01.25

Signature: 

Name in print: Marie Skougaard

Signature of Co-proposers

Place and date: Aarhus, 27.01.25

Signature: 

Name in print: Pernille Koefoed-Nielsen

Place and date: Aarhus, 27.01.25

Signature: 

Name in print: Hans Eiskjær

Place and date:  20/01/2024

Signature: 

Name in print: Kasper Rossing

Place and date

Signature: E-mail included

Name in print: Kaspar Broch

Please send the application by e-mail to: scandiatransplant@rm.dk