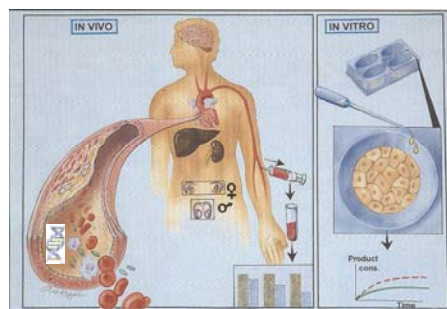
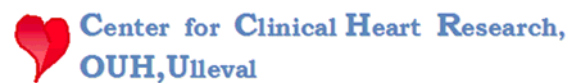


Center for Clinical Heart Research (CCHR)

Department of Cardiology
Medical Division
Oslo University Hospital, Ullevål



Annual Report 2010



<http://ous-research.no/clinicalheartresearch/>

The main aim of the research in CCHR is to continuously improve our competence in clinical translational research, achieve new knowledge broadly related to cardiovascular disease states, initiated by relevant clinical challenges in Oslo University Hospital (OUH) and other health institutions in Helse Sør-Øst.

”Independent clinical, randomized intervention trials including studies on basic mechanisms in pathophysiology of the disease states and the intervention principles”, are the trade mark of CCHR, and are conducted devotedly.

The milieu continuously perform systematically researcher initiated clinical heart research, based on accepted research methodology along with the flow of patients in OUH and Helse Sør-Øst. Projects related to acute myocardial infarction as well as chronic heart disease states like heart failure, atrial fibrillation and diabetes are central.

Studies on mechanisms/translational studies, especially of biochemical and genetic type are of major importance for pathogenetic and therapeutic understanding. Secondary aims in the projects are therefore to improve our knowledge on the pathophysiology of the disease states, especially related to inflammation, haemostasis and peroxidative processes on the circulatory, cellular and genetic levels.

With regard to therapy, controlled life style intervention and individualised drug treatment are focused concepts.

Biobanking, including sampling, processing, freezing/storing according to given quality criteria and procedures are therefore a major part of the activity. To satisfy the high quality demands in this activity we have running costs for qualified technical support and large routine expenses. Many PhD students are allocated to and supervised by the milieu, and several post-doc researchers are closely associated.

The milieu is result oriented. Along with the ongoing projects, in 2010 2 PhD theses were defended and in addition 2 theses were submitted for evaluation (1 was defended in January 2011, and 1 in May 2011). Another 5 theses are supposed to be delivered in 2011. Furthermore, 25 publications in international peer review journals and 28 abstracts on international congresses were published in 2010.

Strategy. All research projects are in line with the strategy for research in Department of Cardiology OUH, and CCHR is a group within the network of Center for Heart Failure Research, OUH.

Location. CCHR is located within Department of Cardiology, close to the patients, which is crucial for the activity. However, serious lack of space represents a limiting factor and a challenging daily life for both PhD students and staff.

Finances. Budgets for the single projects as well as for the running laboratory expenses are totally based on external funding. The economical support from Stein Erik Hagens Foundation for Clinical Heart Research has been of fundamental importance for the activity in 2010.

May 2011

Harald Arnesen (sign)
professor em. dr.med

Ingebjørg Seljeflot (sign)
professor dr. philos

Svein Solheim (sign)
MD post.doc

Organization and working procedures.

Administrative and organizational duties are undertaken in total by the center leaders.

Of most important activity is the regular research meetings every 2-3 weeks at 16.00-18.00. PhD students, post docs and laboratory personell participate together with the professors, and the main projects are reported with progress, results and relevant discussion. Relevant international literature is referred to. Furthermore, external experts on special relevant topics and co-workers from other institutions in addition to intramural experts in epidemiology and biostatistics are invited as lecturers.

Application issues for grants are discussed, and research-related administrative issues are reported, as well as other research meetings, conferences and congresses, reminding of Abstract deadlines etc.

Authors of published papers are congratulated, and the PhD students are encouraged to participate on international congresses, primarily with presentation of own results.

Participation is counting in the PhD program at UoO.

In 2010 14 research meetings were arranged.

Individual supervision of the single PhD student is undertaken in addition.

Ongoing projects, mainly PhD-projects (short version)

"Inflammation and intervention in atherosclerosis with special reference to the metabolic syndrome and obesity".

In this project investigations are undertaken on associations between chronic low-graded inflammation and intervention with diet and/or omega-3 fatty acids. Special focus are given to inflammation in individuals with obesity and/or the metabolic syndrome, in addition to the association between inflammation and clinical cardiovascular events.

Defended for the PhD degree April 16th 2010 (Cand.med. Marius Trøseid).

Supervisors: Professor Harald Arnesen/Professor Ingebjørg Seljeflot

"Glycoprotein 130 (Gp130) – A crosstalk between inflammation, obesity and atherosclerosis".

GP130 is a transmembrane signaling protein with important regulatory functions in several inflammatory reactions. Polymorphisms in the gene coding for Gp130 and their influence on phenotype (circulating proteins), for clinical end-points and for a possible effect of intervention with diet and/or omega-3 fatty acids are studied in a population of 560 men with high risk for coronary heart disease. In addition, studies on genetic expression of inflammatory mediators in adipose tissue from these individuals are undertaken. A predictive score for cardiovascular events based on the genetic expression of these mediators has been launched.

Project for the PhD degree will be submitted in 2011 (Cand.med. Thomas Weiss).

Supervisors: Professor Ingebjørg Seljeflot/Professor Harald Arnesen

In the ASCET study (ASpirin non-responsiveness and clopidogrel Clinical Endpoint Trial)

the primary aim is to investigate if patients with documented coronary heart disease respond adequately on aspirin as their single antithrombotic medication. Thus, clinical relevant endpoints (death, myocardial infarction, new angina pectoris and stroke) are registered in 1001 patients and related to their initial laboratory response to aspirin. Thereafter patients are randomized to continue with aspirin or change to an alternative antiplatelet agent clopidogrel for follow-up after 1 month, 1 year and at end of study after 2 years. A series of laboratory tests on platelet function are performed at all time points, and from a large biobank special focus are related to possible influence of relevant genetic differences in the response to aspirin and clopidogrel, and also on polymorphisms in the genes for other risk factors. (vide infra).

The main study is finished and results presented on "Hot line" at the American Heart Ass Congress, Chicago November 2010. To be submitted as a project for the PhD degree in 2011. (Cand.med. Alf-Åge Pettersen).

Supervisors: Professor Harald Arnesen/Professor Ingebjørg Seljeflot

ASCET-DIA: "Genetic regulation of atherothrombotic risk markers in diabetics with coronary heart disease".

Biobank material and clinical database from the ASCET study (vide supra) are used (n=1001). With application of new methodology possible differences in the genetic regulation of atherothrombotic risk markers (inflammation and haemostasis) in patients with coronary heart disease and diabetes versus non-diabetics are investigated. Special focus are laid on selected genetic polymorphisms' influence on phenotype (circulating proteins) and clinical cardiovascular events.

Project for the PhD degree to be submitted in 2011 (Master of Science Trine Baur Opstad).

Supervisors: Professor Ingebjørg Seljeflot/Professor Harald Arnesen

ASCET-Thrombo: "Evaluation of thrombin generation in patients with coronary heart disease and type 2 diabetes".

In this substudy of the ASCET trial (vide supra), new methodology for ex vivo evaluation of thrombin generation (Endogenous Thrombin Potential with the Calibrated automated thrombogram (CAT)) as a thrombotic marker is evaluated against a traditional in vivo method for thrombin generation (Prothrombin Fragment 1+2) in samples from the 1001 patients. In addition attention is paid to possible gender differences.

Project for Master of Science, defended October 2010 (Medical technologist Vibeke Bratseth).

Supervisors: Professor Ingebjørg Seljeflot/Cand.med. Alf-Åge Pettersen

EXCADI (Exercise training in patients with coronary artery disease and diabetes).

Based on the population from the ASCET study (vide supra) a new study was started aiming at evaluating the effect of systematic physical exercise training in a randomised trial including patients with documented coronary heart disease and diabetes. Primary aims are effect on glucometabolic regulation and markers of atherothrombosis, and power calculation has resulted in the need for 160 patients to be included. A large biobank is founded for additional studies on the molecular level, including genetic expression in samples from adipose tissue. The exercise training is conducted in cooperation with the Norwegian School for Science in Sports, including 2 students for the degree of Master of Science.

Project for the PhD degree (Cand.med. Rune Byrkjeland).

Supervisors: Post doc. Svein Solheim/Professor Ingebjørg Seljeflot/Professor Harald Arnesen

GLUMIIK (Glucometabolic status in patients with acute myocardial infarction).

Patients with acute myocardial infarction has a high prevalence of undiagnosed diabetes. This phenomenon is investigated in 220 patients with acute ST-elevation myocardial infarction (STEMI). The prevalence of "abnormal glucose regulation" in the acute phase and its reproducibility over 3 months are studied for association with clinical cardiovascular endpoints after 1 year. Additional investigations are undertaken for a possible predictivity of selected biomarkers of inflammation and haemostasis.

Project for the PhD degree to be submitted in 2011(Cand.med. Eva Cecilie Knudsen)

Supervisors: Post.doc Geir Øystein Andersen/Professor Ingebjørg Seljeflot

NORDISTEMI (NORwegian Distance ST-Elevation Myocardial Infarction study).

A regional study in Helse Sør-Øst where 240 patients with acute ST-elevation myocardial infarction, all receiving thrombolytic therapy because of long distance(>90 minutes) to the PCI center, were randomized to direct transport to OUH-Ullevål for primary coronary angiography ± PCI or to clinical stabilization at the local hospital for later referral to coronary angiography ± PCI when indicated (according to previous routine). In addition to clinical relevant end-points (death, reinfarction, stroke and revascularizations), health-economic and quality-of-life analyses, a series of biochemical substudies related to inflammation, metabolic disturbances and infarct size (MRI) are undertaken. Project for the PhD degree delivered November 2010. (Cand.med. Ellen Bøhmer, Lillehammer)

Supervisors: Dr.med/post.doc. Sigrun Halvorsen/Professor Harald Arnesen

POSTEMI (Post-conditioning in STEMI treated with primary PCI).

A prospective, randomized trial undertaken at the coronary care unit to investigate the effect of 2 different regimes for PCI therapy in patients with acute ST-elevation myocardial infarction (n=260): traditional opening of the occluded artery or a "step-wise"

opening/occlusion procedure, inducing so-called post-conditioning which is thought to contribute to diminished reperfusion injury after the PCI. The primary aim is infarct size measured with MRI. The mechanisms of post-conditioning are not fully understood, and a series of blood samples along the PCI procedure are gathered to elucidate the biochemical processes related to reperfusion injury (inflammatory, oxidative, apoptotic). Processing of samples, biobanking and biochemical analyses are undertaken at CCHR.

Project for the PhD degree. (Cand.med. Limalanathan Shanmuganath)

Supervisors: Dr.med. Jan Eritsland/Post.doc Geir Ø. Andersen

AMI-SMS (Acute Myocardial Infarction Stem-cell Mobilization Study).

The hypothesis is that autologous stem-cells can induce "self repair" in myocardial infarction. The project comprises substudies from the ASTAMI ("Autologous Stem-cells in Acute Myocardial Infarction") trial (New Engl J Med 2006, 355, 1199) as well as from the PIMI ("PCI In Myocardial Infarction) study.

Main focus is on signalling substances for stem cell mobilization from the bone marrow to the circulation, especially different growth factors and the time to optimal mobilization.

This PhD project will be finished in 2011.Cand.med. Haakon Kill Grøgaard).

Supervisors: Professor Arnfinn Ilebekk/Professor Harald Arnesen

Metalloproteinases and atherosclerosis.

The role of various metalloproteinases in the chronic atherosclerotic process as well as for the acute myocardial infarction is still not clarified. In addition to a proinflammatory component, these proteins seem to play an important role in matrix remodeling and degradation and therefore probably in plaque rupture. Two major MMPs are studied during intervention with stent implantation (PCI), and with diet and omega-3 fatty acids, with possible influence also on clinical end-points.

Altogether 3 publications in international peer-reviewed journals constitute the Thesis to be evaluated for the Medical Student Research Program, Faculty of Medicine, University of Oslo in 2011 (Stud.med. Eline Bredal Furenes).

Supervisors: Professor Ingebjørg Seljeflot/Professor Harald Arnesen/Post doc. Svein Solheim

HINCAB ("Home based Intervention Nursing Coronary Bypass grafting study"). In this joint study with Department of Nursing and Health Sciences at UiO, 203 patients undergoing aorto-coronary bypass graft surgery were randomized to home visits by a specially educated nurse 2 and 4 weeks after surgery or regular follow-up at the hospital and in primary health services. The home visits focused on structured relevant interviews and conversations with special attention on anxiety, depression and general coping. Validated questionnaires were used before the operation and after 6 months, the analyses being performed blindly by expert personell.

Project for the PhD degree defended December 8th 2010 (Cand.Nurs.Sci. Irene Lie)

Supervisors: Dr. philos Eli H. Bunch/Professor Glenys Hamilton/Professor Harald Arnesen

RATAF (RaTe control in Atrial Fibrillation):

So-called "rate control" has in recent years been claimed to be more important than "rhythm control" for patients with Atrial fibrillation. This randomized cross-over project (n=80) studies the effect of different drugs used in rhythm control to evaluate which drug gives optimal ventricular rate and at the same time improved quality-of-life. A biobank is mounted for relevant biochemical analyses. Joint project with Asker & Bærum Hospital, Vestre Viken HF. Project for the PhD degree (Cand.med. Sara Ulimoen).

Supervisors: Dr.med. Arnljot Tveit/Professor Harald Arnesen

BIRKOPP (Long-term follow-up of respiratory and cardiovascular function in former and still active male cross-country skiers).

This is a follow-up study of 122 long distance cross-country skiers recruited from the 56km Birkebeiner race after 28-30 years. The participants were among the best quartile of competitors and represented the follow-up of PhD Håkon Lies thesis from 1985. At follow-up 78 out of 85 subjects still alive participated, initially divided into 3 age groups. Main focus was on cardiac arrhythmias, especially atrial fibrillation, cardiopulmonary functional tests, echocardiographic examination and morbidity and mortality in general.

Project for the PhD degree, and thesis submitted for evaluation August 2010 (Cand.med. Jostein Grimsmo).

Supervisors: Professor Sverre Mæhlum/Professor Harald Arnesen

"Atrial fibrillation - long-term risk predictors and importance for morbidity and mortality".

The project comprises risk factors for atrial fibrillation, especially with echocardiographic examinations in patients after electroconversion (CAPRAF study) and in long distance cross-country skiers (BIRKOPP study). In addition to epidemiological studies on a large database residing in Medical Research Laboratory, OUH Ullevål the project will constitute a PhD project, probably to be finished in 2011. (Cand.med. Irene Grundvold).

Supervisors: Professor Harald Arnesen/Professor Sverre Erik Kjeldsen/Dr.med. Johan Bodegard

Post doc. Projects

"Post ASTAMI".

Dr.med. Svein Solheim who defended his PhD thesis in 2008 has received a 50% post doc. scholarship from Helse Sør-Øst on the project "Thrombosis and haemostatic variables in STEMI patients after treatment with PCI and autologous bone marrow stem cells".

Based on the observation of 15% mural left ventricular thrombus in the ASTAMI (Autologous Stem cell Transplantation in Acute Myocardial Infarction) trial during dual antiplatelet therapy, studies on the coagulation system, systemic and at an expression level from blood samples in the biobank from this trial, are undertaken. Supplementary in vitro studies in cell cultures are further planned.

Post doc. project (MD PhD Svein Solheim)

In the **CAPRAF (Candesartan in the Prevention of Relapsing Atrial Fibrillation)** trial in patients with atrial fibrillation no effect of the angiotensin-II-receptor antagonist candesartan on relapse of atrial fibrillation after initial successful electroconversion was observed (Thesis cand med Arnljot Tveit defended 2008). However, based on biobanking during the study, new light was shed on mechanisms of the arrhythmia itself and the tendency to relapse after electroconversion, mainly related to endothelial function and remodelling of the atrium.

Supplementary substudies are still ongoing.

Post doc. project (MD PhD Arnljot Tveit)

ABAF (Asker and Bærum Atrial Fibrillation study). A population study to map the prevalence of atrial fibrillation (AF) in individuals above 75 years. A total of 1200 individuals participated and AF was diagnosed in 12%. A case-control study (60 cases/120 controls) is conducted to study risk factors, quality of life, socio-economic conditions etc..A biobank is established in ABAF and a series of analyses are performed to increase the understanding of trigger mechanisms and potentially new therapeutic principles. Genetic aspects are also studied. The biochemical analyses are undertaken at CCHR.

Post doc. project (MD PhD Arnljot Tveit)

LEAF (Safety and efficacy of Levosimendan in patients with Acute myocardial infarction complicated with symptomatic left ventricular Failure).

A randomized, placebo-controlled study to investigate the effect and safety of the new drug Simdax (levosimendan) in patients with PCI-treated STEMI with complicating heart failure. Infusion of levosimendan for 24 hours is compared to placebo, and a broad specter of biochemical analyses are performed in addition to tests of cardiac function, repeatedly during the 6 weeks follow-up. Sampling, processing, biobanking and the biochemical analyses are undertaken at CCHR.

Post.doc. project (MD PhD Geir Ø. Andersen)

Other projects with support/supervision from CCHR

NORCAST (Norwegian Cardiac Arrest Survival Trial)

Combined clinical-neurological, neurophysiological, neuroradiological and biochemical markers in prognostication after cardiac and/or respiratory arrest. A prospective observation study at Oslo University Hospital, Ullevål.

In this multidisciplinary study performed in acute seriously ill patients, 250 patients are planned to be included. Blood samples are taken and processed at CCHR for analysis of a series of biomarkers especially related to neuro-inflammation and thrombotic risk markers in the very acute phase and also after 3 days in those staying alive. The patients are followed for one year. A Steering Committee representing the different disciplines are involved, with *professor Kjetil Sunde, Department of Surgical Intensive Care Unit* as the leader of the project in close collaboration with the Acute Coronary Care Unit by Geir Ø. Andersen *ao.* The project is so far daily handled by *PhD-student Espen Rostrup Nakstad* and one additional PhD student is planned into the project.

Diabetes in children and atherosclerosis development.

Patients with type-1 diabetes from childhood have 20-30 times increased risk for premature death from cardiovascular diseases compared to non-diabetics. In the present study, initiated from Department of Pediatrics/Oslo Diabetes Center, 330 children/youth with type-1 diabetes are compared with 120 healthy controls matched for age and gender to investigate early signs of atherosclerosis as measured with various methods (anatomical, physiological, biochemical). Both groups will be followed for 5 and 10 years. All blood sampling/processing and facilities for biochemical translational research (biobanking, analyses) are undertaken at CCHR.

PhD project (Cand.med. Hanna Dis Margeirsdottir)

Supervisor: Professor Knut Dahl-Jørgensen

Effect of benfothiamin in type-1 diabetes ("Influence of oral benfothiamine supplementation on the progression of micro-and macrovascular complications in type-1 diabetes").

This principle is being tested in a randomized, placebo-controlled study over 2 years in 70 patients with long-standing type-1 diabetes. The aim is to evaluate whether this simple "drug" (vitamin B-type) might influence positively the glucose regulation in such patients. The participants undergo neurophysiological examination and a biobank is established to study any influence on markers of atherosclerosis at CCHR. Also, monocytes are isolated for *ex vivo* studies on potential effects of thiamin.

Post doc. David Frazer and Professor Kristian Hanssen are primarily responsible for the project.

Deleterious cardiac effects of long-time use of anabolic steroids evaluated with different cardiological methods.

The study is based on the assumption that doping with anabolic steroids increase the risk for and prevalence of ischemic heart disease. Body-builders with confessed use of anabolic steroids are compared to weight-lifting athletes not using dop. A multitude of cardiological methods (E-ECG, echocardiography, coloured tissue-Doppler, coronary CT) are used, and a series of biomarkers, including variables in coagulation and platelet activation (in detail by flowcytometry and aggregation) are studied. The project is initiated from OUH Aker with all biochemical investigations being performed at CCHR.

PhD project (Cand.med. Paul Vanberg)

Supervisor: Professor Dan Atar

HJUS ("HJertesvikt i Ullevål Sykehus").

In this randomized study the possible positive effect of systematic physical exercise for 4 months in patients with manifest heart failure is evaluated with walk test, exercise ECG, biochemical markers of heart failure (neurohormones), and hospitalizations after 1 year.

Physical therapist Birgitta Nilsson defended her thesis for the PhD degree on the main results in 2009. Based on the biobank a series of extended biochemical studies, especially on inflammation and endothelial function, are undertaken.

(Cand.med. Rune Byrkjeland/Professor Ingebjørg Seljeflot).

Pulmonal arterial hypertension and right ventricle function in patients with chronic obstructive lung disease (COLD).

This study is aimed to evaluate non-invasive 3-D echo cardiography and Doppler method and ergospirometry, to diagnose pulmonal arterial hypertension (PAH) and systolic function of right ventricle in patient with COLD, and compare with magnetic resonance imaging (MR) and right ventricle cateterization. Biomarkers both venous and mixed arterial/venous, as related to the diagnosis and also to the severity of COLD (GOLD-calssification), are collected. The laboratory analysis and biochemical supervision will be undertaken at CCHR. The study is performed at OUS Aker.

PhD project (Cand.med. Janne Mykland Hilde)

Supervisor: Amanuensis Kjetil Steine

BAMI ("Biobanking in patients with Acute Myocardial Infarction").

In this joint project between the the Cardiac Care Unit, General Cardiology Section and CCHR in Department of Cardiology, an extended biobank is mounted along with prospectively registered clinical data and will be the basis for studies on predictive markers for later clinical events. Consecutive patients with STEMI are included after consent. At the end of 2010 about 1000 patients have been included and a PhD project on baseline biochemical variables is started. Furthermore, when about 3000 patients are included, genetic analyses will be undertaken. All logistics for the biochemical translational research are undertaken by CCHR. (Professor Ingebjørg Seljeflot)

A Steering committee for BAMI is established.

Laboratory Methodology

Of relevant and resource demanding methods for the presented projects should specially be mentioned (in addition to sampling and processing for biobanking after SOPs):

- Platelet function testing with aggregometry and flow-cytometry in addition to "bedside" screening tests
- ELISA with large costs for reagents
- HPLC, specially used for elucidation of endothelial function and peroxidation
- Studies on gene expression (RT-PCR) in several projects
- Studies on genetic polymorphisms (PCR) in several projects

For several methods our laboratory instruments are placed in different facilities in cooperating laboratories because of serious lack of space "at home". This represents a limiting factor and a challenging daily life for both PhD students and staff and therefore for the research activity.

Theses defended for the PhD degree in 2010.

Marius Trøseid, MD

Studies on inflammation and atherosclerosis in the metabolic syndrome.

Dissertation: April 2010

Supervisors: Professor Harald Arnesen /Professor Ingebjørg Seljeflot/

Irene Lie, Cand.Sci.

Implementation of a home-based psychoeducative intervention in the early rehabilitation phase after coronary artery bypass graft surgery. A randomised controlled trial focusing on anxiety and health related quality of life.

Dissertation: December 2010

Supervisors: Professor Eli Haugen Bunch/Professor Harald Arnesen/Professor Glenys Hamilton

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Articles

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The association between metabolic syndrome and infarct size in patients with acute myocardial infarction

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PubMed 20429699 SFX ISI 000280211200011 (Details)

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