



RCSI

UNIVERSITY
OF MEDICINE
AND HEALTH
SCIENCES



RCSI Clinical Research Centre

Improving Patient Care and
Inspiring the next generation
of Clinical Researchers

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YEAR
2000



CLINICAL RESEARCH
CENTRE OPENED

799

STUDIES
CONDUCTED



26,675

PATIENT VISITS

300

EXPERTLY TRAINED
CLINICAL RESEARCH
STAFF THROUGH THE
CRC ANNUALLY



TOP 10%

CRC'S GLOBAL
RANKING FOR
CITATIONS IN
CLINICAL MEDICINE



DIRECTORS' MESSAGE



PROFESSOR FERGAL O'BRIEN

DEPUTY VICE CHANCELLOR FOR RESEARCH AND INNOVATION, RCSI

RCSI's research mission is informed by clinical problems which ensures a focus on translation of knowledge into better therapies and interventional strategies for the benefit of patients. The RCSI Clinical Research Centre plays a pivotal role in enabling this ambition. Working with the CRC and our world-class network of healthcare professionals and scientists, together with industry and academic and clinical partners, we are focused on the continued growth of the Centre, enabling it to increase participation in national and international multicentre clinical trial activity. This is aligned with our core institutional mission to educate, nurture and discover for the benefit of human health.



PROFESSOR GER CURLEY

DIRECTOR, RCSI CLINICAL RESEARCH CENTRE

Health outcomes for patients are better where clinical research is actively supported and embedded within the healthcare system. The Royal College of Surgeons in Ireland Clinical Research Centre (RCSI-CRC) supports doctors and other healthcare professionals based at Beaumont Hospital perform studies to develop and evaluate new treatments and diagnostics in our core clinical areas, capitalising on the unique cohort of patients in Beaumont Hospital as the leading centre nationally in many therapeutic areas. Our vision is to be a world-class Clinical Research Centre, facilitating our investigators to lead pivotal clinical trials, improve patient care and inspire the next generation of clinical researchers. We have established a core team of experienced staff in RCSI CRC who are in position to facilitate impactful clinical research and lead national education initiatives. We look forward to working with academic and commercial partners to deliver patient-focused, world-class clinical research into the future.

DIRECTORS' MESSAGE



DR FIONNUALA KEANE

DIRECTOR OF OPERATIONS, RCSI CLINICAL RESEARCH CENTRE

The RCSI CRC provides facilities, expertise and a comprehensive range of support systems to enable investigators to conduct clinical research to the highest standards. Through its quality management system, the Centre supports research in a broad spectrum of clinical areas and has developed particular expertise in core areas which align with the clinical strengths of the services provided in Beaumont Hospital.

National and international networking and collaboration are fundamental to research quality and growth, and RCSI CRC is committed to active engagement with research partners to enhance patient care and outcomes.



AILBHE CULLEN

DIRECTOR OF NURSING, RCSI CLINICAL RESEARCH CENTRE

Over the past decade our focus on building our quality systems, nursing expertise, and research facilities has enabled us to support Investigators in carrying out complex clinical trials in a variety of therapeutic areas.

Our feasibility and set up support, links with disease networks, and close links with the clinical institution have facilitated the year on year growth of our clinical research study portfolio and patient activity in the CRC.

The RCSI CRC continues to provide ICH GCP training courses and other short research courses, which are available to our research teams and the wider research community.

ABOUT RCSI

Founded in 1784, RCSI's aim is to develop healthcare leaders who make a difference worldwide. RCSI is a community of academic, research, clinical and professional staff working collaboratively to lead the world to better health. Our exciting mission "To educate, nurture and discover for the benefit of human health".

RCSI is home to Ireland's largest undergraduate medical school and also provides undergraduate education in pharmacy and physiotherapy. The college delivers postgraduate education and professional training through the school of postgraduate studies, and the institute of leadership; through its Faculties of Radiologists, Dentistry, Nursing and Midwifery, and Sports and Exercise Medicine; and through the National Surgical Training Centre.

Innovating for a Healthier Future 2023-2027 is RCSI's five-year strategic plan. Through it, RCSI will enhance human health by meeting the health workforce needs of society, creating the insights and inventions that drive health improvements, and working in partnership with patients and the public in support of better health and well-being for all. The strategy unites the RCSI community in supporting the UN Sustainable Development Goals – with a particular focus on Goal 3, which targets good health and well-being.

For each of the last six years, RCSI has been positioned in the Top 300 of universities worldwide in the Times Higher World University Rankings. We are proud to announce that RCSI has ranked first in the world for "Good Health and Well-being" in the Times Higher Education SDG Impact

Rankings 2023. This reflects our commitment to supporting people of all ages to live healthy lives and our work to promote the concepts of well-being and positive health. Our values of Respect, Collaboration, Scholarship and Innovation continue to unite and direct our purpose.





ABOUT OUR RESEARCH

RCSI recognises that excellence in research is critical to the quality of its educational activities, its credibility, and, overall, to its mission to enhance human health. RCSI's research strategy aims to build upon its strength in translational biomedical and clinical research to deliver transformational, high impact changes in health care. Targeting both Irish national and EU funding, along with increased collaboration with industry, is a major part of the RCSI research strategy. Forging increased collaboration between RCSI PIs and industry is of critical importance to achieving success in this area.



RCSI CLINICAL RESEARCH CENTRE - OVERVIEW

The RCSI Clinical Research Centre provides facilities and expertise to enable investigators to conduct clinical research to the highest standards. The first academic research centre in Ireland, the centre opened in September 2000 to provide clinical research support to RCSI investigators and to investigators affiliated with RCSI.


The centre is located on the Beaumont Hospital campus, one of RCSI's principal teaching hospitals in Dublin. This location supports the centre's translational focus and provides ready opportunities for clinician-based research studies.

Since opening in September 2000, the centre has had more than 26,675 patient visits. During this time, the activities of the centre have developed a cohort of highly skilled and trained research nurses with the attendant expertise to enable clinical research.

The aim of the RCSI Clinical Research Centre is to advance medical knowledge of illness and improve patients' care. By working in partnership with academia, funding agencies and the commercial sector, we are contributing to the development of life-enhancing therapies through basic research and clinical trials. The centre achieves this by providing a physical infrastructure and support, primarily through study coordination, and research nurse expertise.

Research is conducted by consultant physicians from Beaumont Hospital who invite their patients to participate in research activities. Since opening, the centre has conducted studies in many specialties, including:

- » **Critical Care Medicine and Anaesthesia** – studies in Acute Lung Injury and Traumatic Brain Injuries
- » **Endocrinology** – studies of Steroid Metabolism Disorders; Pituitary and Adrenal Disease
- » **Geriatric Medicine** – device study to prevent serious injury in falls in the elderly
- » **Infectious Diseases** – clinical trials of treatments for HIV and COVID-19
- » **Medical Devices** – inhaler device, ocular micrometer measurement and hip device investigations
- » **Nephrology and Transplant surgery** – studies in chronic kidney disease; Rare Kidney Disease Biobank
- » **Neurology** – clinical trials of medications for the treatment of Motor Neurone Disease and Multiple Sclerosis; Epilepsy Research; Myotonic Dystrophy
- » **Respiratory Medicine** – Asthma, Alpha 1 Antitrypsin Deficiency, Interstitial Pulmonary Fibrosis Clinical Trials
- » **Stroke Medicine** – clinical trials of medication in stroke



THE CENTRE HAS A COHORT OF HIGHLY SKILLED AND TRAINED RESEARCH NURSES WITH THE EXPERTISE TO ENABLE CLINICAL RESEARCH.

CLINICAL RESEARCH CENTRE - RECENT HIGHLIGHTS

PUBLICATIONS – INCA Paper in LANCET - Lancet Respir Med. 2023 Jul;11(7):591-601. doi: 10.1016/S2213-2600(22)00534-3. Epub 2023 Mar 21. Use of digital measurement of medication adherence and lung function to guide the management of uncontrolled asthma (INCA Sun): a multicentre, single-blinded, randomised clinical trial
Elaine Mac Hale and INCA Research Team, RCSI CRC

EDUCATION PROGRAMMES – The RCSI CRC is the leading provider nationally of education and training in clinical research practice with over 325 people completing its courses in 2023

FUNDING AWARD – RCSI CRC is in receipt of a HRB award supporting the provision of the Study Feasibility and Activation Management service in the CRC

COVID RESEARCH – RCSI CRC were leaders in the delivery of pivotal National and International COVID research

NEW THERAPEUTIC AREA – Poly Cystic Ovary Syndrome (PCOS) Clamp trials – mediating the adverse metabolic health outcomes of androgen excess in women with PCOS led by Professor Michael O Reilly

PPI INITIATIVES – including PPI participation on the RCSI CRC Governance board, establishment of a PPI panel for the CRC and provision of a PPI advisory service to PI's in the CRC.



AS THE REGULATORY FRAMEWORK FOR CLINICAL RESEARCH BECOMES MORE COMPLEX THE WORK OF THE RCSI CLINICAL RESEARCH CENTRE STAFF HAS ADJUSTED ACCORDINGLY TO SUPPORT INVESTIGATORS WITHIN THIS ENVIRONMENT.

CLINICAL TRIAL CAPABILITIES

The centre has facilities to conduct phase II to phase IV clinical trials; IMP studies and clinical investigations of medical devices. We support academic and commercial led studies.

- » **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- » **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- » **Phase IV:** studies are conducted after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

QUALITY AND GOVERNANCE

As the regulatory framework for clinical research becomes more complex, the work of the RCSI Clinical Research Centre staff has adjusted accordingly to support investigators within this environment.

These include formal systems for:

- » Training in Good Clinical Practice (GCP)
- » Comprehensive management of quality systems
- » Study Sponsorship via RCSI Sponsorship Office
- » Governance and Oversight

Key areas of support to the physician investigators include a management structure to oversee and perform clinical trials and investigations. The research nurse team has extensive experience in working with ethical and regulatory requirements and is optimally positioned to deal with the flexibility required to respond to the rapidly changing demands of a dynamic research environment.



STAFF EXPERTISE

The staff at the Clinical Research Centre includes a cohort of expert, highly skilled and educated senior research nurses with experience in a variety of therapeutic areas, a Director, a Director of Operations, a Director of Nursing, a Director of Research Nurse Education, a Quality and Regulatory Affairs Manager, a Study Feasibility and Activation Manager and an administrator working alongside the many medical teams engaged in research activities in the centre.

Experts in clinical research nursing

The centre has dedicated nurses engaged full time in clinical trials with exposure to a wide variety of both academic and clinical research, research of IMP and medical devices.

The centre takes a leading role in supporting research nurse education and development, from the provision of postgraduate educational opportunities, to the leadership and ongoing support of the Irish Research Nurses and Midwives Network (IRNM). RCSI CRC is the leading provider of good clinical practice (GCP) training, not only for investigational medicinal product (IMP) trials, but also GCP in medical device research and sponsor responsibilities. The provision of train-the-trainer courses for other centres has allowed these institutions to adapt RCSI CRC courses for their own use locally. The centre also provides continuing education for research nurses and midwives and other healthcare disciplines in the coordination and management of clinical research.

**THE CENTRE TAKES A LEADING
ROLE IN SUPPORTING
RESEARCH NURSE EDUCATION
AND DEVELOPMENT**





SERVICES AND FACILITIES

Services and supports

From basic concept to project implementation, investigator services provided include:

- » Dedicated consulting room space
- » Dedicated research office space
- » Feasibility & study set up support
- » Advice on study set-up and ongoing conduct
- » Cohort of nurses with variety of research expertise
- » Full or partial study co-ordination
- » Quality and operations supports to research teams
- » Biological sample handling and storage facility
- » Access to RCSI Biobanking service

Facilities

- » **Clinical suite**
Patient consultations and study visits
- » **Day ward**
Patient day visits (with oxygen, suction and resuscitation trolley facilities)
- » **Spirometry Suite**
For conducting spirometry testing patient consultations and study visits
- » **IMP Management**
Facilities for IMP Management
- » **Sample Processing Lab**
Processing of blood and biological samples; storage of biological samples (-20° and -80° freezers)
- » **Pharmacy Space**
Storage of temperature monitored clinical trial medications, ambient and refrigerated, under secure conditions
- » **Study Equipment storage areas**
Storage of study equipment and kits under secure conditions



INDUSTRY AND ACADEMIC LINKS AND PARTNERS

At the RCSI Clinical Research Centre (RCSI CRC) we welcome collaborative partnership. Through these partnerships, patients and investigators benefit through enhanced patient care and outcomes. We also work closely with industry, clinical, academic and charitable organisations and, through our extensive external partnerships, we are working on a range of clinical trials and investigations in novel diagnostics, medical devices and pharmacological therapeutics.

Through collaborative partnership with RCSI CRC, partners can benefit from, and access, specific groups of researchers, as well as help to grow research capacity and capability in areas of shared interest. Furthermore, by collaborating, we can ensure that research benefits patients, the public and Irish economy.



RCSI CLINICAL RESEARCH CENTRE - CASE STUDIES



A SYSTEM TO CLASSIFY TREATABLE TRAITS IN ASTHMA STUDY

PROFESSOR RICHARD COSTELLO

Building on prior research conducted by Professor Richard Costello in asthma assessment and adherence inhaled medications using digital technology, Professor Costello has developed a study to evaluate adults who have ongoing symptoms despite empiric treatment for asthma.

The overarching aim of this study is to evaluate whether the diagnosis and assessment of symptoms can be conducted simultaneously using digital technology and remote monitoring.

This study involves detailed clinical assessment, lung function measurement and blood testing, conducted across four visits in a 3 month period.

During this period, participants monitor their lung function twice a day at home with a digital lung function monitor, while a device attached to their inhaler quantifies treatment use at this time. This information assists Clinicians in making accurate assessments and diagnosis in a time efficient manner for both the patient and the clinician.

The clinical assessment, lung function measurement and visits take place in the RCSI CRC in Beaumont Hospital which has the facilities and expertise required to support this study.

RCSI CLINICAL RESEARCH CENTRE - CASE STUDIES



DIMOXIS STUDY

PROFESSOR MICHAEL O'REILLY

The DIMOXIS study is a study examining the role of different subclasses of steroids called androgens on metabolic health in women with polycystic ovary syndrome (PCOS).

The study was funded by the Health Research Board as an emerging clinician scientist award to Professor Michael O'Reilly, clinical Associate Professor in RCSI and Consultant Endocrinologist.

Women with PCOS are at an increased risk of metabolic complications such as diabetes and cardiovascular disease.

A new class of androgens called 11-oxygenated androgens are now known to make up the majority of all androgens in women with PCOS, and emerging evidence suggests that these steroids may play a role in mediating a higher risk of diabetes in this condition.

The DIMOXIS study has recently completed recruitment and the metabolic study visits have now been completed. Biomaterial and data analysis are currently ongoing.

All metabolic phenotyping visits in DIMOXIS took place in the RCSI Clinical Research Centre. 20 women with PCOS underwent comprehensive metabolic

assessment using gold standard techniques, including hyperinsulinaemic-euglycaemic clamp testing, stable isotope studies and muscle biopsies. Assessments were completed before and after receiving an oral androgenic precursor for 7 days as a probe to perturb metabolism.

The clinical assessment, lung function measurement and visits take place in the RCSI CRC in Beaumont Hospital which has the facilities and expertise required to support this study.

The RCSI CRC was critical to the delivery of this complex metabolic study, providing clinical bed spaces, facilities for storage of biomaterials and a pool of trained research nurses. This work will provide new insights into how different types of androgenic steroids may impact on the risk of metabolic disease in women with PCOS.

RCSI CLINICAL RESEARCH CENTRE - CASE STUDIES



COVID 19

DR EOGHAN DEBARRA

Clinical trials can be challenging to run. The COVID-19 pandemic stopped almost all activity, but new clinical questions needed to be answered. The RCSI CRC rose to the challenge and enabled the Beaumont site to become Ireland's highest recruiting site in the WHO sponsored Global Solidarity trial of therapeutic interventions for COVID-19. The team ably navigated the process to site readiness and was able to deploy experienced research nurses to ensure smooth, safe and accurate adherence to the protocol, despite constantly shifting backdrop of clinical aspects of the disease, national and international policies and restrictions on movements. The structures, and in particular research nursing expertise, meant that new co-investigators could

be easily brought on board and that internal monitoring could be performed.

Following this success the team were able to utilise knowledge and experience to become a very active contributor to emerging Sub-National and National biobanks and to successfully respond to calls from the EU to participate in vaccination studies to provide insights into optimal regimens. Throughout the RCSI CRC was able to provide the human and physical infrastructure to allow the research to be conducted to the highest standards. Our group looks forward to the continued development of the RCSI CRC and approaches global collaborations on future studies with increasing confidence in the site ability to deliver.

RCSI CLINICAL RESEARCH CENTRE - CASE STUDIES



A STUDY OF ALPHA-1 ANTITRYPSIN (AAT), AN ANTI-INFLAMMATORY PROTEIN AS A TREATMENT OPTION FOR CRITICALLY ILL COVID-19 PATIENTS PROFESSORS GER CURLEY AND GERRY MCELVANEY

In March 2020, Professor Gerard Curley and Professor Gerry McElvaney and their teams at the Royal College of Surgeons in Ireland (RCSI) Clinical Research Centre established the first approved Irish-led clinical trial of a medicine for COVID-19. The study investigated the effects of using an anti-inflammatory protein, alpha-1 antitrypsin (AAT), to treat COVID-19 patients with acute respiratory distress syndrome (ARDS).

ARDS is a highly inflammatory state characterised by airway damage and respiratory failure. Patients with severe ARDS are at increased risk of death. Treatment options for COVID-19 patients who have ARDS are limited and are largely supportive rather than therapeutic.

This study was a multi-site randomised controlled trial and AAT was administered to patients with COVID-19-associ-

ated ARDS, with the aim of reducing inflammation. Study results indicated that treatment with AAT led to decreased inflammation after one week. The study also found that the treatment was safe and well tolerated.

This study was undertaken at the early stages of the COVID-19 pandemic during a challenging time. The COVID-19 pandemic presented unique challenges for clinical research teams. Rapid protocol development and subsequent review by key contributors was required in order to expedite the initiation of the trial. Staff at the RCSI Clinical Research Centre (CRC) assisted in navigating the regulatory and ethical approval processes, and RCSI CRC nurses played a vital role in assisting with study procedures including randomisation, and management of the investigational medicinal product (IMP).

RCSI CLINICAL RESEARCH CENTRE - CASE STUDIES



TUDCA-ALS CLINICAL TRIAL PROFESSOR ORLA HARDIMAN

Tauroursodeoxycholic acid as add-on treatment in patients affected by amyotrophic lateral sclerosis (ALS)

The TUDCA-ALS clinical trial (Tauroursodeoxycholic acid as add-on treatment in patients affected by amyotrophic lateral sclerosis (ALS)) led by PI Prof Orla Hardiman sought to investigate the safety and efficacy of Tauroursodeoxycholic acid in patients diagnosed with Amyotrophic Lateral

Sclerosis or ALS, also often referred to as Motor Neurone Disease or MND.

The primary outcome for TUDCA-ALS clinical trial was to slow disease progression, as measured by a reduction in patients ALSFRS-R (ALS Functional Rating Scale-Revised) score. This is one of the questionnaires that is used to measure the primary endpoint for ALS which identifies disease function and progression in patients with ALS.



RCSI CLINICAL RESEARCH CENTRE - CASE STUDIES

TUDCA-ALS was a phase III, multicentre, randomised, double blind, placebo controlled, parallel-group study. The study was funded by the Horizon 2020 grant. Recruitment began in November 2019, and continued throughout the COVID-19 pandemic, with final screening in May of 2021. Twenty-six patients were screened for the study, of which 21 were randomised. The study ran for 18 months in the double-blind

phase and concluded with last patient, last visit in July of 2022. Fifteen of the 21 randomised patients completed the double-blind phase, despite the additional complications surrounding the COVID-19 pandemic, and nature of progression of ALS.

During the COVID 19 pandemic we were able to continue this important clinical trial with the support of the Standard Operating Procedures of the CRC.

An Open Label Extension (OLE) for the TUDCA-ALS study was offered to patients who completed the double-blind study, and were able to participate at the time of study start date. Nine patients out of the 15 who completed the TUDCA-ALS double blind study, continued on to the TUDCA-ALS OLE. The OLE also ran for 18 months, and concluded in January 2024.







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