https://web.archive.org/web/20191214125501/https://clinicaltrials.gov/ct2/show/NCT02898610 June 1, 2023 at 1:28 PM EDT
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12 captures 14 Dec 2019 - 8 Dec 2022 2018 14 2019 2021 About this capture

Colchicine for Prevention of Vascular Inflammation in Non-cardio Embolic Stroke (CONVINCE)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT02898610

Recruitment Status : Recruiting
First Posted : September 13, 2016
Last Update Posted : September 25, 2017

See Contacts and Locations

Sponsor:
University College Dublin

Collaborators:
Health Research Board, Ireland
Irish Heart Foundation
University of Limerick
University of Edinburgh
National University of Ireland, Galway, Ireland
Universitat de Lleida
Universitaire Ziekenhuizen Leuven
University of Athens

Information provided by (Responsible Party):
University College Dublin

Study Description

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Brief Summary:

This study evaluates the use of Colchicine in adults over 40 years of age who have suffered an ischaemic stroke or transient ischaemic attack NOT caused by cardiac embolism or other defined causes. Patients will be randomised to 0.5 mg/day of Colchicine plus usual care, or to usual care alone.

To investigate the efficacy of low dose colchicine (0.5mg/day) plus usual care (defined as antiplatelet, lipid-lowering, antihypertensive treatment, and appropriate lifestyle advice) compared with usual care alone to prevent non-fatal recurrent ischaemic stroke, myocardial infarction, cardiac arrest, hospitalization for unstable angina and vascular death after ischaemic stroke or transient ischaemic attack (TIA) not caused by cardiac embolism or other defined causes unrelated to atherosclerosis

Condition or disease	Intervention/treatment	Phase
Ischemic Attack, Transient Stroke	Drug: Colchicine	Phase 3

MURRAY & POOLE EXHIBIT 1045

Detailed Description:

Inflammation is a key pathophysiological contributor to unstable atherosclerotic plaque and thrombo-embolic events, stroke, myocardial infarction, and vascular death. Internationally, clinical trials are targeting atherosclerotic inflammation in patients with coronary disease using methotrexate, colchicine, and canukinumab.

Aims:

The primary aim is to compare low-dose colchicine (0.5mg/day) plus usual care, to usual care alone, to prevent non-fatal recurrent ischaemic stroke and coronary events and vascular death after non-severe, noncardioembolic TIA/stroke. Secondary objectives will investigate safety of low-dose colchicine, and efficacy for each component of the primary outcome, fatal and non-fatal events, disabling and non-disabling stroke, effect modification by prespecified subgroups, and impact on direct health care costs, adjusted for quality-adjusted life years.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	2623 participants
Allocation:	Randomized
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Prevention
Official Title:	CONVINCE - (COlchicine for preventioN of Vascular Inflammation in Non- CardioEmbolic Stroke) - a Randomised Clinical Trial of Low-dose Colchicine for Secondary Prevention After Stroke
Study Start Date :	December 12, 2016
Estimated Primary Completion Date :	October 2021
Estimated Study Completion Date :	October 2021

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Transient Ischemic Attack

Drug Information available for: Colchicine

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Colchicine treatment Colchicine 0.5mg/day plus usual care for 60 months	Drug: Colchicine
No Intervention: Usual Standard of care alone Normal standard of care remains for these patients	

Outcome Measures

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Primary Outcome Measures :

1. Recurrence of non-fatal ischemic stroke [Time Frame: any time within 60 month]

   Any recurrence of non-fatal ischemic stroke

2. on-fatal Major Cardiac event [Time Frame: any time within 60 months]

   Non-fatal hospitalization for unstable angina, myocardial infarction, cardiac arrest

3. Vascular death [Time Frame: 60 months]

   Fatal ischemic stroke, myocardial infarction, cardiac arrest

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	40 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Written informed consent consistent with ICH-GCP guidelines and local laws signed prior to all trial-related procedures.
2. Age 40 years or greater
3. Either,
   - ischaemic stroke without major disability (modified Rankin score 3 or less)
   - or high-risk TIA
4. Qualifying stroke/TIA probably caused by large artery stenosis, small artery occlusion (lacunar stroke), or cryptogenic embolism, with cardiac embolism or other defined stroke mechanism deemed unlikely in the opinion of the treating physician.
5. GFRgreater than or equal to 50 ml/min.
6. In the opinion of the treating physician, patient is medically-stable, capable of participating in a randomised trial, and willing to attend follow-up.

Exclusion Criteria:

1. Cardio-embolic stroke/TIA, probably caused by identified atrial fibrillation (permanent or paroxysmal), in the opinion of the treating physician.
2. Cardio-embolic stroke/TIA probably caused by other identified cardiac source (intra-cardiac thrombus, endocarditis, metallic heart valve, low ejection fraction <30%), in the opinion of the treating physician.
3. Stroke/TIA caused by dissection, endocarditis, paradoxical embolism, drug use, venous thrombosis, within 48 hours aftercarotid or cardiac surgery, hypercoagulability states, migraine, or inherited cerebrovascular disorders (eg. Fabry's disease, CADASIL), in the opinion of the treating physician.
4. History of myopathy or myalgias with raised creatine kinase (CK) on statin therapy.
5. Blood dyscrasia defined as anaemia (haemoglobin <10g/dL), thrombocytopenia (platelet count <150 x109/L) or leucopenia (white cell count <4 x109/L) at randomisation.
6. Impaired hepatic function (transaminases greater than twice upper limit of normal) at randomisation.
7. Concurrent treatment with moderate or strong CYP3A4 inhibitors (clarithromycin, erythromycin, telithromycin, other macrolide antibiotics, ketoconazole, itraconazole, voriconazole, ritonavir, atazanavir, indinavir, other HIV protease inhibitors, verapamil, diltiazem, quinidine, digoxin, disulfiram) or P-gp inhibitors (cyclosporine) at randomisation.
8. Symptomatic peripheral neuropathy and pre-existing progressive neuromuscular disease
9. Inflammatory bowel disease (Crohn's or ulcerative colitis) or chronic diarrhoea.

9. Dementia, sufficient to impair independence in basic activities of daily living.

10. Active malignancy, known hepatitis B or C, or HIV infection prior to qualifying stroke/TIA.

11. Impaired swallow preventing oral administration of study medication. 12. History of poor medication compliance. 13. Unlikely to comply with study procedures and follow-up visits due to severe or fatal comorbid illness or other factor (eg. inability to travel for follow up visits), in opinion of randomising physician.

14. Pregnancy, breast-feeding, or pre-menopausal women 15. Patient concurrently participating in another clinical trial with an investigational drug or device, or use of investigational drug within 30 days or 5 half-lives before the Screening visit (whichever is longer) 16. Known allergy or sensitivity to colchicine.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02898610***

Contacts

Contact: Prof Peter Kelly isctn@ucd.ie

Contact: Prof Sean Murphy isctn@ucd.ie

Locations

Belgium

AZ Sint Jan — **Not yet recruiting**
Brugge, Belgium
Principal Investigator: Geert Vanhooren

AZ Groeninge Kortrijk — **Not yet recruiting**
Kortrijk, Belgium
Principal Investigator: Peter Vanacker

CHC Leige — **Recruiting**
Leige, Belgium
Principal Investigator: Philippe Desfontaines

UZ Leuven — **Recruiting**
Leuven, Belgium
Principal Investigator: Robin Lemmens

Ireland

Cork University Hospital — **Not yet recruiting**
Cork, Ireland
Principal Investigator: Simon Cronin

Letterkenny University Hospital — **Not yet recruiting**
Donegal, Ireland
Principal Investigator: Jose Miranda

Beaumont Hospital — **Recruiting**
Dublin, Ireland
Principal Investigator: David Williams

Connolly Hospital, Blanchardstown — **Recruiting**
Dublin, Ireland
Principal Investigator: Eamon Dolan

Mater Misericordiae University Hospital — **Recruiting**
Dublin, Ireland
Contact: Sean Murphy

St James's Hospital — **Recruiting**
Dublin, Ireland
Principal Investigator: Joe Harbison

St Vincent's University Hospital — **Recruiting**
Dublin, Ireland

Contact: Tim Cassidy

The Adelaide & Meath Hospital, Dublin incorporting the NCH — **Recruiting**
Dublin, Ireland
Principal Investigator: Ronan Collins

Galway University Hospital — **Recruiting**
Galway, Ireland
Principal Investigator: Martin O'Donnell

Naas General Hospital — **Not yet recruiting**
Kildare, Ireland
Principal Investigator: Paul OBrien

University Hospital Limerick — **Recruiting**
Limerick, Ireland
Principal Investigator: John McManua

Our Lady of Lourdes, Drogheda — **Recruiting**
Louth, Ireland
Principal Investigator: Martin Mulroy

Mayo University Hospital — **Not yet recruiting**
Mayo, Ireland
Principal Investigator: Tom O'Malley

Sligo University Hospital — **Recruiting**
Sligo, Ireland
Principal Investigator: Paula Hickey

South Tipperary General Hospital, Clonmel — **Recruiting**
Tipperary, Ireland
Principal Investigator: Christina Donnellan

University Hospital Waterford — **Recruiting**
Waterford, Ireland
Principal Investigator: George Pope

Spain

Hospital de Sant Pau — **Not yet recruiting**
Barcelona, Spain
Principal Investigator: Joan Marti Fabgreas

Hospital del Mar — **Not yet recruiting**
Barcelona, Spain
Principal Investigator: Elisa Cuadrado

Hospital de Arnau de Vilanova — **Not yet recruiting**
Lleida, Spain
Principal Investigator: Francisco Purroy

Sponsors and Collaborators

University College Dublin

Health Research Board, Ireland

Irish Heart Foundation

University of Limerick

University of Edinburgh

National University of Ireland, Galway, Ireland

Universitat de Lleida

Universitaire Ziekenhuizen Leuven

University of Athens

Investigators

Study Director: Prof Peter Kelly Mater Hospital

More Information

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Responsible Party:	University College Dublin
ClinicalTrials.gov Identifier:	NCT02898610 History of Changes
Other Study ID Numbers:	2015-004505-16
First Posted:	September 13, 2016 Key Record Dates
Last Update Posted:	September 25, 2017
Last Verified:	September 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Yes
Plan Description:	A summary report of the trial will be provided to the Ethics Committees and relevant Regulatory Authority within as per national legal requirements in participating countries

Additional relevant MeSH terms:

- Stroke
- Ischemic Attack, Transient
- Inflammation
- Cerebrovascular Disorders
- Brain Diseases
- Central Nervous System Diseases
- Nervous System Diseases
- Vascular Diseases
- Cardiovascular Diseases
- Pathologic Processes
- Brain Ischemia
- Colchicine
- Gout Suppressants
- Antirheumatic Agents
- Tubulin Modulators
- Antimitotic Agents
- Mitosis Modulators
- Molecular Mechanisms of Pharmacological Action
- Antineoplastic Agents

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For Patients and Families | For Researchers | For Study Record Managers

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