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Secondary stroke prevention through pathway management

Submission date	Recruitment status	[ ] Prospectively registered
08/03/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/03/2021	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/07/2024	Circulatory System	

Plain English summary of protocol

Background and study aims

Every year, more than 795,000 people in the United States have a stroke. Stroke-related costs in the United States came to nearly $46 billion between 2014 and 2015. This total includes the cost of health care services, medicines to treat stroke, and missed days of work. Stroke is a leading cause of serious long-term disability and reduces mobility in more than half of stroke survivors aged 65 and over. In February 2020, the Global Research Report looked at ICM adoption barriers for cryptogenic stroke. Over 100 cardiologists/electrophysiologists and neurologists in the United States reported 70% have significant care pathway challenges; 50% reported no existing care pathway. A clinical need for care pathway creation exists. This study is designed to evaluate the care pathway for patients with a cryptogenic (unknown origin) stroke, large artery atherosclerosis, and small vessel occlusion events in the hospital setting. The intention is to use the results to design another study to further research potential solutions and evaluate the impact on both clinical and economic stroke outcomes.

Who can participate?

Patients aged 18 years or over with a cryptogenic stroke or large artery atherosclerosis or small vessel occlusion hospitalization between 2017 – 2019

What does the study involve?

The study is collecting de-identified data on all subjects who meet the inclusion criteria at participating sites in the United States. Economic and clinical data from initial patient assessment until 180 days after hospitalization will be used to assess cryptogenic stroke, large artery atherosclerosis, and small vessel occlusion hospitalizations to identify potential areas for improvement.

What are the possible benefits and risks of participating?

The study is classified as an observational, non-significant risk study. Because this is a retrospective study in which de-identified data will be collected from participating sites, there are no known or foreseeable risks. The information gained from this study could result in improved cryptogenic stroke care pathways in the future.

Where is this study run from?
Medtronic (USA)

When is the study starting and how long is it expected to run for?
June 2020 to March 2024

Who is funding the study?
Medtronic (USA)

Who is the main contact?
Jessica Mikacevich, jessica.m.mikacevich@medtronic.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316927

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MDT20034, IRAS 316927

Study information

Scientific Title
SeconDary Stroke PreVEntion ThRough Pathway ManagemenT (DiVERT Stroke)

Acronym
DiVERT Stroke

Study objectives

Current hypothesis as of 29/12/2021:
Medtronic will conduct a qualitative and quantitative assessment of cryptogenic stroke, large artery atherosclerosis, and small vessel occlusion hospitalizations at the participating clinical study sites to baseline the current short-term clinical and economic outcomes and identify potential areas for improvement.

The intention is to use the results of the Phase I research to design a DiVERT Stroke Phase II study to further investigate and propose potential stroke care pathway solutions that may impact both clinical and economic stroke outcomes.

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Previous hypothesis:
Medtronic will conduct a qualitative and quantitative assessment of cryptogenic stroke hospitalizations at the participating clinical study sites to baseline current short-term clinical and economic outcomes and identify potential areas for improvement.

The intention is to use the results of the Phase I research to design a DiVERT Stroke Phase II study to further research potential solutions and evaluate the impact on both clinical and economic stroke outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/12/2020, WCG Institutional Review Board (IRB) (1019 39th Ave SE, Suite 120, Puyallup, WA , Puyallup, 98374, United States of America; +1 (0)855 818 2289 ; clientservices@wcgirb.com), ref: 20203787

Current ethics approval as of 04/10/2022:
1. Approved 01/09/2022, HRA and Health and Care Research Wales (HCRW) (Castlebridge 4, 15-19 Cowbridge Rd E, Cardiff, CF11 9AB, Wales, UK; +44 (0)2920 230457; approvals@hra.nhs.uk, HCRW.approvals@wales.nhs.uk), ref: 22/HRA/3471
2. Approved 27/12/2020, renewed 11/11/2021, WCG Institutional Review Board (IRB) (1019 39th Ave SE, Suite 120, Puyallup, WA 98374, USA; +1 (0)855 818 2289; clientservices@wcgirb.com), ref: 20203787

All centres will seek ethics approval before performing any study-related activities. Site ethics approval may be ceded to WCG Institutional Review Board (IRB).

Previous ethics approval:
1. Approved 27/12/2020, WCG Institutional Review Board (IRB) (1019 39th Ave SE, Suite 120, Puyallup, WA 98374, USA; +1 (0)855 818 2289; clientservices@wcgirb.com), ref: 20203787
2. Approved 26/10/2022, WCG Institutional Review Board (IRB) (1019 39th Ave SE, Suite 120, Puyallup, WA 98374, USA; +1 (0)855 818 2289; clientservices@wcgirb.com), ref: 20203787
3. Approved 21/03/2023, WCG Institutional Review Board (IRB) (1019 39th Ave SE, Suite 120, Puyallup, WA 98374, USA; +1 (0)855 818 2289; clientservices@wcgirb.com), ref: 20203787
4. Approved 19/10/2021, CommonSpirit Health Research Institute IRB (198 Inverness Drive West, Englewood, CO 80112, USA; +1 (0)844 626 2299; CHIRB@catholichealth.net)
5. Approved 11/11/2021, CommonSpirit Health Research Institute IRB (198 Inverness Drive West, Englewood, CO 80112, USA; +1 (0)844 626 2299; CHIRB@catholichealth.net)

6. Approved 09/02/2022, CommonSpirit Health Research Institute IRB (198 Inverness Drive West, Englewood, CO 80112, USA; +1 (0)844 626 2299; CHIRB@catholichealth.net)
7. Approved 25/04/2022, CommonSpirit Health Research Institute IRB (198 Inverness Drive West, Englewood, CO 80112, USA; +1 (0)844 626 2299; CHIRB@catholichealth.net)
8. Approved 26/10/2022, CommonSpirit Health Research Institute IRB (198 Inverness Drive West, Englewood, CO 80112, USA; +1 (0)844 626 2299; CHIRB@catholichealth.net)
9. Approved 08/03/2021, USF Research & Innovation - Research Integrity Compliance IRB (3702 Spectrum Blvd, Ste 155, Tampa, FL 33612, USA; +1 (0)813 974 5638; RSCH-arc@usf.edu)
10. Approved 22/06/2021, USF Research & Innovation - Research Integrity Compliance IRB (3702 Spectrum Blvd, Ste 155, Tampa, FL 33612, USA; +1 (0)813 974 5638; RSCH-arc@usf.edu)
11. Approved 01/09/2022, HRA and Health and Care Research Wales (4, 15 - 19 Cowbridge Rd E, Castlebridge, Cardiff CF11 9AB, UK; +44 (0)2920 230457; healthandcareresearch@wales.nhs.uk)

Study design
Retrospective non-randomized multi-center clinical study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Stroke

Interventions
Current intervention as of 29/12/2021:
The DiVERT Stroke Phase I Clinical Study is a retrospective data collection study investigating hospital admissions of cryptogenic stroke, large artery atherosclerosis, and small vessel occlusion patients and the related care pathway. De-identified patient-level data, as outlined below, will be extracted from medical records and hospital cost/charge accounting. This data will be linked with patient-level data from the AHA® Get with the Guidelines® (GWTG) hospital-based quality improvement program to provide a longitudinal view of each patient's care, outcomes and costs. Additionally, sites will provide Medtronic with documentation of their current stroke care pathways, standard order sets, and other protocols related to stroke patient care.

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Previous intervention as of 20/05/2021:
The DiVERT Stroke Phase I Clinical Study is a retrospective study with a specific focus on collecting data around the stroke and related care pathway. De-identified patient-level data, as

outlined below, will be extracted from medical records and hospital cost/charge accounting. This data will be linked with patient-level data from the AHA® Get with the Guidelines® (GWTG) hospital-based quality improvement program to provide a longitudinal view of each patient's care, outcomes and costs. Additionally, sites will provide Medtronic with documentation of their current stroke care pathways, standard order sets, and other protocols related to stroke patient care.

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Previous intervention:
The DiVERT Stroke Phase I Clinical Study is a retrospective study with a specific focus on collecting data around the cryptogenic stroke and related care pathway. De-identified patient-level data, as outlined below, will be extracted from medical records and hospital cost/charge accounting. This data will be linked with patient-level data from the AHA® Get with the Guidelines® (GWTG) hospital-based quality improvement program to provide a longitudinal view of each patient's care, outcomes and costs. Additionally, sites will provide Medtronic with documentation of their current stroke care pathways, standard order sets, and other protocols related to stroke patient care.

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 29/12/2021:
The following data will be collected for all subjects within 12 months prior to the index stroke hospitalization through medical records review:
1. Medical history
2. Alcohol consumption
3. CHA2DS2 VASc Score (most recent within 12 months prior to index hospitalization)
4. Lab tests: CRP, BNP (most recent within 12 months prior to index hospitalization)

The following data will be collected for all subjects at index stroke hospitalization through medical records review:
1. Hospitalization dates (e.g., admission, discharge)
2. Neurology diagnostic testing
3. EP consultation
4. Short-term/external monitors, wearables, and/or ICM recommendation (if applicable)
5. Short-term/external monitors, wearables, and/or ICM use (if applicable)

The following data will be collected for all subjects at follow-up visits through 180 days post-index stroke hospitalization (i.e. discharge) through medical records review:
1. Discharge location (SNF, inpatient, home, etc.)
2. Prescribed stroke-related follow-up cadence (office and remote)
3. Stroke-related follow-up dates
4. Neurology diagnostic testing

The following economic data evaluated through medical records and hospital cost/charge accounting data for all subjects at 30-, 60-, 90-, 180-days post-hospital discharge:
1. Total cost of stroke diagnostic work-up for index hospitalization and through 180 days follow-up
2. Total cost of index stroke hospitalization
3. Total cost short-term/external monitoring

4. Total cost pre- and post-ICM insertion
5. Total cost of care 30, 60, 90, 180 days post-stroke, including cardiovascular disease and atrial fibrillation (AF) healthcare utilization costs
6. Total cost of stroke readmissions and stroke recurrences, including healthcare utilization

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Previous primary outcome measures:
The following information will be collected through medical records and hospital cost/charge accounting data within 12 months prior to the index stroke hospitalization:
1. Medical history
2. Alcohol consumption
3. CHA2DS2 VASc Score (most recent within 12 months prior to index hospitalization)
4. Lab tests: CRP, BNP (most recent within 12 months prior to index hospitalization)

The following information will be collected through medical records and hospital cost/charge accounting data at index stroke hospitalization:
1. Hospitalization dates (e.g., admission, discharge)
2. Neurology diagnostic testing
3. EP consultation
4. Short-term/external monitors, wearables, and/or ICM recommendation (if applicable)
5. Short-term/external monitors, wearables, and/or ICM use (if applicable)

The following information will be collected through medical records and hospital cost/charge accounting data at follow-up visits through 180 days post-index stroke hospitalization (i.e. discharge):
1. Prescribed stroke-related follow-up cadence (office and remote)
2. Stroke-related follow-up dates
3. Neurology diagnostic testing

Secondary outcome measures

Current secondary outcome measures as of 29/12/2021:
The previous secondary outcome measures are now primary outcome measures, therefore there are currently no secondary outcome measures.

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Previous secondary outcome measures:
Evaluated through medical records and hospital cost/charge accounting data at 30-, 60-, 90-, 180-days post-hospital discharge:
1. Total cost of stroke diagnostic work-up for index hospitalization and through 180 days follow-up
2. Total cost of index stroke hospitalization
3. Total cost short-term/external monitoring
4. Total cost pre- and post-ICM insertion
5. Total cost of care 30, 60, 90, 180 days post-stroke, including cardiovascular disease and atrial fibrillation (AF) healthcare utilization costs
6. Total cost of stroke readmissions and stroke recurrences, including healthcare utilization

Overall study start date

15/06/2020

Completion date

19/03/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/09/2022:
US Inclusion Criteria:
1. Patients with a cryptogenic stroke or large artery atherosclerosis or small vessel occlusion hospitalization between 2017 – 2019
2. Age ≥18 years

UK Inclusion Criteria:
1. Patients with a cryptogenic stroke or large artery atherosclerosis or small vessel occlusion hospitalization between 2019-2020. If ischemic stroke sub-type classification proves to be difficult (i.e., small sample size), patients with an ischemic stroke from 2017-2019 will be included.
2. Age ≥18 years

Previous inclusion criteria from 20/05/2021 to 01/09/2022:
1. Patients with a cryptogenic stroke or large artery atherosclerosis or small vessel occlusion hospitalization between 2017 – 2019
2. Age ≥18 years

Previous inclusion criteria:
1. Patients with a cryptogenic stroke hospitalization defined by ICD-10 I63.9 between 2017 – 2019
2. Age ≥18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The number of subjects enrolled in this retrospective study will be dependent on the number of subjects at the participating sites that meet the inclusion and exclusion criteria (estimate 7200)

Total final enrolment
6536

Key exclusion criteria
Current exclusion criteria as of 20/05/2021:
Does not meet inclusion criteria

Previous exclusion criteria:
1. Any history of the following through index stroke:
1.1. Lacunar stroke
1.2. Large artery atherosclerosis
1.3. Diagnosis of AF or atrial flutter
1.4. Ablation for AF or atrial flutter
1.5. OAC use
1.6. Methamphetamines drug use
1.7. Mechanical heart valves
1.8. Rheumatic heart disease
1.9. Mitral stenosis
1.10. Ischemic cardiomyopathy
1.11. Dilated cardiomyopathy
1.12. ST-elevation MI
1.13. Vasculitis
1.14. End stage renal disease
1.15. ICM implant prior to index event
2. VT Ablation within 30 days of index event
3. Non-AF left atrial or ventricular ablation within 30 days of index event
4. Any of the following within 30 days pre to 90 days post index stroke:
4.1. Carotid artery stenting
4.2. Carotid endarterectomy
4.3. Carotid artery stenosis or occlusion
4.4. ASD closure device insertion

Date of first enrolment
19/02/2021

Date of final enrolment
20/12/2023

Locations

Countries of recruitment
England

United Kingdom

United States of America

Study participating centre
HCA Midwest
10500 Quivira Rd
Overland Park
United States of America
66215

Study participating centre
CHI Memorial
2525 Desales Ave
Chattanooga
United States of America
37404

Study participating centre
University of South Florida/Tampa General
2 Tampa General Circle
Tampa
United States of America
33606

Study participating centre
St. David's
919 E 32nd St
Austin
United States of America
78705

Study participating centre
TriStar Centennial
2300 Patterson St
Nashville
United States of America
37203

Study participating centre
Trident
9330 Medical Plaza Dr
Charleston
United States of America
29406

Study participating centre
Franciscan Neurology Associates
1608 South J St
Tacoma
United States of America
98405

Study participating centre
Franciscan Neurology Associates - Federal Way (St. Francis)
34503 9th Ave S, Suite 230
Federal Way
United States of America
98003

Study participating centre
Franciscan Neurology Associates - Gig Harbor (St. Anthony)
6401 Kimball Drive, 2nd Floor
Gig Harbor
United States of America
98335

Study participating centre
Franciscan Neurology Associates - Silverdale (St. Michael)
1950 Northwest Myhre Road, 3rd floor
Silverdale
United States of America
98383

Study participating centre
Franciscan Neurology Associates - Burien (St. Anne)
16259 Sylvester Road SW, Suite 503
Burien
United States of America
98166

Study participating centre
Franciscan Neurology Associates - Lakewood (St. Clare)
11311 Bridgeport Way SW, Suite 100
Lakewood
United States of America
98499

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal

Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Medtronic (United States)

Sponsor details
8200 Coral Sea Street NE
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+1 (0)612 219 7361
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Sponsor type
Industry

Website
http://www.medtronic.com/us-en/index.html

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 29/12/2021:
1. The protocol and the statistical analysis plan will be publicly available at study completion, or earlier upon request
2. Primary study results will be submitted for publication after the primary objective is met
3. Planned publication targets include: high-impact peer-reviewed journals, neurology conferences, cardiology conferences
4. Planned publication types include but are not limited to: primary publications, ancillary publications, and design publications in the format of manuscripts, abstracts, and posters

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Previous publication and dissemination plan:
1. Protocol can be sent and the statistical analysis plan will be sent upon completion of the document
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as this is a retrospective data pull based on inclusion/exclusion criteria.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		10/07/2024	17/07/2024	No	No