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Secondary stroke prevention through pathway management

Submission date 22/09/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/10/2022	**Overall study status** Completed	
Last Edited 27/01/2025	**Condition category** 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. These totals include 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. Of over 100 cardiologists/electrophysiologists and neurologists in the United States, 70% reported having significant care pathway challenges; 50% reported having no existing care pathway. A clinical need for care pathway creation exists. The intention of the DiVERT Stroke II Study (derived from DiVERT Phase I study learnings) is to evaluate how a multi-disciplinary care pathway affects short-term clinical and economic outcomes.

Who can participate?
Patients 18 years of age or older with a cryptogenic stroke or large artery atherosclerosis or small vessel occlusion hospitalization between 2023-2024 at participating clinical study sites.

What does the study involve?
The DiVERT Stroke II study care pathway is prospective, and patient data collection is retrospective, similarly, to DiVERT Stroke Phase I (ISRCTN87407792) data collection. The purpose of the study is to assess the DiVERT Stroke II study care pathway at hospitals that participated in DiVERT Stroke Phase I. The study will investigate care pathway adherence and evaluate short-term clinical and economic outcomes. Medtronic will conduct a qualitative and quantitative assessment of stroke hospitalizations at the participating clinical study sites.

What are the possible benefits and risks of participating?
The information gained from this study may result in the improvement of stroke care by developing and utilizing pathways in the future. Because data will be retrospectively collected and de-identified by the sites before retrieval at Medtronic, there are no known foreseeable risks.

Where is this study run from?
Medtronic (USA)

When is the study starting and how long is it expected to run for?
June 2022 to January 2025

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
Ms Jessica Mikacevich

Contact details
8200 Coral Sea Street Northeast
Mounds View
United States of America
55112
+1 651 315 2719
jessica.m.mikacevich@medtronic.com

Type(s)
Scientific

Contact name
Ms Dalia Richmond

Contact details
8200 Coral Sea Street Northeast
Mounds View
United States of America
55112
+1 612 219 7361
dalia.m.richmond@medtronic.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
MDT22040

Study information

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

Acronym
DiVERT Stroke Phase II

Study objectives
Current study hypothesis as of 23/08/2023:

Medtronic will conduct a qualitative and quantitative assessment of stroke hospitalizations at the participating clinical study sites. This assessment will evaluate short-term clinical and economic outcomes and pathway adherence of the DiVERT Stroke II study care pathway.

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Previous study hypothesis:

Medtronic will conduct a qualitative and quantitative assessment of stroke hospitalizations at the participating clinical study sites. This assessment will evaluate short-term clinical and economic outcomes and pathway adherence of the DiVERT Stroke Phase II care pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 29/08/2022, WCG IRB (1019 39th Ave SE, Suite 120, Puyallup, WA 98374, USA; +1 855 818 2289; clientservices@wcgirb.com), ref: 20224624
2. Approved 21/03/2023, WCG IRB (1019 39th Ave SE, Suite 120, Puyallup, WA 98374, USA; +1 855 818 2289; clientservices@wcgirb.com), ref: 20224624
3. Approved 31/07/2023, WCG IRB (1019 39th Ave SE, Suite 120, Puyallup, WA 98374, USA; +1 855 818 2289; clientservices@wcgirb.com), ref: 20224624
4. Approved 06/04/2023, USF Research & Innovation – Research Integrity & Compliance IRB (3702 Spectrum Blvd Suite 165 Tampa, FL 33612, USA; +1 813 974 5638; RSCH-arc@usf.edu)

Study design
Multicenter interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Interventions
Current interventions as of 23/08/2023:

The DiVERT Stroke II study care pathway will enable physicians to use stroke etiology, presentation characteristics, neuroimaging factors and other clinical risk factors to recommend no cardiac monitoring, external cardiac monitoring, or internal cardiac monitoring. The stroke care pathway leverages current standard of care best practices and poses no safety risks for participating clinical study sites due to the quality improvement nature of the clinical study. All other care aspects including follow-up activity will remain the same as the standard of care. No referral methods will be utilized. No randomization process will be utilized. No screening methods will be utilized.

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Previous interventions:

The DiVERT Stroke Phase II care pathway will enable physicians to use stroke etiology, presentation characteristics, neuroimaging factors and other clinical risk factors to recommend no cardiac monitoring, external cardiac monitoring, or internal cardiac monitoring. The stroke care pathway leverages current standard of care best practices and poses no safety risks for participating clinical study sites due to the quality improvement nature of the clinical study. All other care aspects including follow-up activity will remain the same as the standard of care. No referral methods will be utilized. No randomization process will be utilized. No screening methods will be utilised.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 23/08/2023:

1. The following information will be collected within 180 days prior to the index stroke hospitalization from patient records and measured through chart review:
1.1. Medical history
1.2. Alcohol consumption
1.3. CHA2DS2 VASc Score (if congestive heart failure +1, if hypertension +1, if age ≥75 +2, if diabetes +1, if previous stroke +2, if vascular disease +1, if age 65 to 74 +1, and if sex category (female) +1) (most recent within 180 days prior to index hospitalization, if available)

1.4. Lab Tests: CRP (C-reactive protein), BNP (brain natriuretic peptide) (most recent within 180 days prior to index hospitalization, if available)

2. The following information will be collected during the index stroke hospitalization from patient records:
2.1. Hospitalization Dates measured by admission and discharge dates
2.2. Neurology diagnostic testing measured through chart review
2.3. EP Consultation measured through chart review
2.4. Short-term/external monitors, wearables, and/or ICM recommendation (if applicable /available) measured through DiVERT Stroke Phase II Care Pathway and chart review
2.5. Short-term/external monitors, wearables, and/or ICM use (if applicable/available) measured through DiVERT Stroke Phase II Care Pathway and chart review

3. The following information will be collected at follow-up visits through 180 days post-index stroke
hospitalization (i.e., discharge) from patient records and measured through chart review:
3.1. Discharge location (SNF (skilled nursing facility), inpatient, home, etc.)
3.2. Prescribed stroke-related follow-up cadence (office and remote)
3.3. Stroke-related follow-up dates
3.4. Neurology diagnostic testing

4. Economic information to be collected from patient records and measured via claims data and chart review include:
4.1. Total cost of stroke diagnostic work-up for index hospitalization and through 180 days of follow-up
4.2. Total cost of index stroke hospitalization
4.3. Total cost short-term/external monitoring
4.4. Total cost pre- and post-ICM insertion
4.5. Total cost of care 30, 60, 90, 180 days post-stroke, including cardiovascular disease and AF healthcare utilization costs
4.6. Total cost of stroke readmissions and stroke recurrences, including healthcare utilization

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Secondary outcome measures
There are no secondary outcome measures

Overall study start date
10/06/2022

Completion date
20/01/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/08/2023:

1. Patients with a cryptogenic stroke or large artery atherosclerosis or small vessel occlusion hospitalization between 2023 and 2024
2. Age ≥18 years

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Previous inclusion criteria:

1. Patients with a cryptogenic stroke or large artery atherosclerosis or small vessel occlusion hospitalization between 2022 and 2024
2. Age ≥18 years

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
We anticipate there will be 1,500 patients included in the analysis cohort. If sample size is less than 1,500 patients, summary statistics will be provided. The number of subjects captured retrospectively will be dependent on the number of subjects at the site that meet the inclusion criteria.

Total final enrolment
1756

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
21/08/2023

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
United States of America

Study participating centre
Overland Park Regional Medical Center
10500 Quivira Road
Overland Park
United States of America
66215

Study participating centre
Kansas City Heart Rhythm Institute
5100 W 110th St. Suite 200
Overland Park
United States of America
66211

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

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

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

Study participating centre
Research Medical Center
2330 East Meyer Blvd Suite T509
Kansas City
United States of America
64132

Study participating centre
University of South Florida Health including Tampa General Hospital
2 Tampa General Circle
Tampa
United States of America
33606

Sponsor information

Organisation

Medtronic (United States)

Sponsor details
8200 Coral Sea Street Northeast
Mounds View
United States of America
55112
+1 612 219 7361
karah.neisen@medtronic.com

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
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

Intention to publish date
31/10/2025

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