

# Secondary stroke prevention through pathway management

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
22/09/2022	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
12/10/2022	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
27/01/2025	Circulatory System	<input type="checkbox"/> Record updated in last year

## 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](mailto:jessica.m.mikacevich@medtronic.com)

## Contact information

**Type(s)**  
Public

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**Type(s)**  
Scientific

**Contact name**  
Ms Dalia Richmond

**Contact details**  
8200 Coral Sea Street Northeast  
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55112  
+1 612 219 7361  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**

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

**Study type(s)**

Other

**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(s)

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  $\geq 75$  +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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### **Key secondary outcome(s)**

There are no secondary outcome measures

### **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  $\geq 18$  years

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Previous inclusion criteria:

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### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Sex**

All

### **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)

**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

**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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes