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RECRUITING

Evolut™ EXPAND TAVR II Pivotal Trial

ClinicalTrials.gov ID NCT05149755

Sponsor Medtronic Cardiovascular

Information provided by Medtronic Cardiovascular (Responsible Party)

Last Update Posted 2023-09-14

Study Overview

Brief Summary

Obtain safety and effectiveness data to support indication expansion for the Medtronic TAVR System to include patients with moderate, symptomatic AS.

Detailed Description

Multi-center, international, prospective, randomized study. Subjects will be randomized to either transcatheter aortic valve replacement (TAVR) with the Evolut PRO+ TAVR System, or Evolut FX System, and guideline-directed management (GDMT) or GDMT alone.

Official Title

Evolut™ EXPAND TAVR II Pivotal Trial

Conditions

Aortic Stenosis Symptomatic | Moderate Aortic Valve Stenosis

Intervention / Treatment

- Device: Medtronic Evolut PRO+ TAVR System, or Evolut FX TAVR System, and guideline-directed management and therapy (GDMT)

Other Study ID Numbers

- D00411092

Study Start (Actual)

2022-04-27

Primary Completion (Estimated)

2026-02

Study Completion (Estimated)

2034-12

Enrollment (Estimated)

650

Study Type

Interventional

Phase

Not Applicable

Resource links provided by the National Library of Medicine NIH NLM

Genetic and Rare Diseases Information Center resources: Aortic Valve Stenosis

Other U.S. FDA Resources

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Study Contact

Name: Hang Nguyen
Phone Number:
+1765262832
Email: hang.t.nguyen@medtronic.com

Study Contact Backup

Name: Hang Nguyen
Email: rs.expandii@medtronic.com

United States

Alabama Locations

Birmingham, Alabama, United States, 35233
Recruiting
University of Alabama at Birmingham (UAB) Hospital
Contact: Mustafa Ahmed, M.D.
Contact: Dylan Addis, M.D.

Arizona Locations

Phoenix, Arizona, United States, 85016
Recruiting
Abrazo Arizone Heart Hospital

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies.

Eligibility Criteria

Description

Key Inclusion Criteria:

- Moderate AS, defined as follows by transthoracic echo (TTE) at rest:
  - Max aortic velocity ≥ 3.0 m/sec and < 4.0 m/sec, and
  - Mean aortic gradient ≥ 20.0 mmHg and < 40.0 mmHg, and
  - AVA >1.0 cm2 and < 1.5 cm2
- NYHA class ≥ II and symptoms of AS, including but not limited to:
  - Dyspnea at rest or on exertion
  - Fatigue
  - Angina
  - Syncope in the absence of another identifiable cause
- LVEF > 20% by 2-D echo
- Any of the following
  - HF event or hospitalization for heart failure within 1 calendar year prior to qualifying echo
  - NT proBNP ≥ 600 pg/ml (or BNP 80 pg/ml) measured within 6 months prior to or within 2 weeks after qualifying echo,
  - Global longitudinal strain ≤15% (absolute value) at qualifying echo, or
  - E/e' (average of medial and lateral velocities) ≥ 14.0 at qualifying echo

Key Exclusion Criteria:

- Age < 65 years
- Class I indication for cardiac surgery
- Sievers Type 0 or Type 2 bicuspid aortic valve or Sievers Type 1 bicuspid aortic valve with ascending aorta diameter > 4.5 cm
- Not anatomically suitable for transfemoral TAVR with the trial device
- In need of and suitable for coronary revascularization per Heart Valve Team
- Documented history of cardiac amyloidosis

— Show less

Ages Eligible for Study

65 Years and older (Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

Expand all / Collapse all

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Medtronic Evolut PRO+, or Evolut FX,TAVR System, & guideline-directed management & therapy (GDMT) Medtronic Evolut PRO+ TAVR or Evolut FX TAVR Systems, & guideline-directed management & therapy	Device: Medtronic Evolut PRO+ TAVR System, or Evolut FX TAVR System, and guideline-directed management and therapy (GDMT) • Patients will have a Transcatheter Aortic Valve Replacement (TAVR) with either an Evolut PRO+ TAVR, or Evolut FX TAVR, heart valve, and given clinical site-determined guideline-directed management and therapy (GDMT).
No Intervention: Clinical site determined guideline-directed management and therapy (GDMT) alone Clinical site determined guideline-directed management and therapy (GDMT) alone	

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Composite rate of all-cause mortality, all-stroke, life threatening or fatal bleeding, acute kidney injury, hospitalization due to device or procedure-related complication, or valve dysfunction requiring reintervention.	Life threatening or fatal bleeding is defined as BARC Type 3 or 4 and acute kidney injury is defined as VARC-3 Stage IV.	30 days
Composite rate of all-cause mortality, heart failure hospitalization or event, or medical instability leading to aortic valve replacement or re-intervention.		2 years

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Proportion of subjects alive and with moderately improved quality of life (≥ 10 points in KCCQ summary score from baseline)		1 year
Composite of all-cause mortality and heart failure hospitalizations or events.		2 years
Composite of all-cause mortality, all-stroke, or unplanned CV hospitalizations		2 years
Heart failure hospitalizations or events.		2 years
All-cause mortality		2 years
Unplanned cardiovascular hospitalizations		2 years
Days alive and free of unplanned cardiovascular hospitalizations		2 years

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Medtronic Cardiovascular

Collaborators

No information provided

Investigators

- Principal Investigator: Paul Sorajja, MD, Allina Health System
- Principal Investigator: Josep Rodes-Cabau, MD, Fondation IUCPQ
- Principal Investigator: Stephan Windecker, Prof., Inselspital, Universitätsspital Bern

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2021-11-24
First Submitted that Met QC Criteria
2021-11-24
First Posted
2021-12-08

Study Record Updates

Last Update Submitted that met QC Criteria
2023-09-12
Last Update Posted
2023-09-14
Last Verified
2023-09

More Information

Record History

Expand all / Collapse all

Terms related to this study

Keywords Provided by Medtronic Cardiovascular

aortic
stenosis
symptomatic
moderate
valve
TAVR

Additional Relevant MeSH Terms

Pathological Conditions, Anatomical
Aortic Valve Disease
Heart Valve Diseases
Heart Diseases
Cardiovascular Diseases
Ventricular Outflow Obstruction
Aortic Valve Stenosis
Constriction, Pathologic

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies A U.S. FDA-Regulated Device Product

Yes

Unapproved/Uncleared Device

Yes

Study Documents

No study documents available

RECRUITING

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ClinicalTrials.gov ID NCT05149755

Sponsor Medtronic Cardiovascular

Information provided by Medtronic Cardiovascular (Responsible Party)

Last Update Posted 2023-09-14

Trial Contacts

Contacts KOMJE	1. Contact: Hang Nguyen Phone Number: +17652426932 Email Address: hang.t.nguyen@medtronic.com 2. Contact: Hang Nguyen Email Address: rs.expandii@medtronic.com

Study Record Dates

First Submitted KOMJE	2021-11-24
First Posted KOMJE	2021-12-08
Last Update Posted	2023-09-14
Last Verified	2023-09

Outcome Measures

Change History	See all versions of this study
Primary (Current) KOMJE **(Submitted: 2023-01-05)**	• Composite rate of all-cause mortality, all-stroke, life threatening or fatal bleeding, acute kidney injury, hospitalization due to device or procedure-related complication, or valve dysfunction requiring reintervention. [Time Frame: 30 days] ◦ Life threatening or fatal bleeding is defined as BARC Type 3 or 4 and acute kidney injury is defined as VARC-3 Stage IV. • Composite rate of all-cause mortality, heart failure hospitalization or event, or medical instability leading to aortic valve replacement or re-intervention. [Time Frame: 2 years]
Primary (Original) KOMJE **(Submitted: 2021-11-24)**	• Composite of all-cause mortality, all-stroke, life threatening or fatal bleeding, acute kidney injury, hospitalization due to device or procedure-related complication, or valve dysfunction requiring reintervention [Time Frame: 30 days] ◦ Life threatening or fatal bleeding is defined as BARC Type 3 or 4 and acute kidney injury is defined as VARC-3 Stage IV • Composite of all-cause mortality, heart failure event, or aortic valve replacement or reintervention [Time Frame: 2 years]
Secondary (Current) KOMJE **(Submitted: 2022-12-15)**	• Proportion of subjects alive and with moderately improved quality of life (≥ 10 points in KCCQ summary score from baseline) [Time Frame: 1 year] • Composite of all-cause mortality and heart failure hospitalizations or events. [Time Frame: 2 years] • Composite of all-cause mortality, all-stroke, or unplanned CV hospitalizations [Time Frame: 2 years] • Heart failure hospitalizations or events. [Time Frame: 2 years] • All-cause mortality [Time Frame: 2 years] • Unplanned cardiovascular hospitalizations [Time Frame: 2 years] • Days alive and free of unplanned cardiovascular hospitalizations [Time Frame: 2 years]
Secondary (Original) KOMJE **(Submitted: 2021-11-24)**	• Proportion of subjects alive and with moderately improved quality of life (≥ 10 points in KCCQ summary score from baseline) [Time Frame: 1 year] • Composite of all-cause mortality and heart failure events (inclusive of hospitalizations) [Time Frame: 2 years] • Composite of all-cause mortality, all-stroke, or unplanned CV hospitalizations (inclusive of all aortic valve replacement (AVR)) [Time Frame: 2 years] • Heart failure events (inclusive of hospitalizations) [Time Frame: 2 years] • All-cause mortality [Time Frame: 2 years] • Unplanned cardiovascular hospitalizations (exclusive of AVR) [Time Frame: 2 years] • Days alive and free of unplanned cardiovascular hospitalizations (inclusive of all AVR) [Time Frame: 2 years]
Other Pre-specified (Current)	Not provided
Other Pre-specified (Original)	Not provided

Trial Description

Brief Title KOMJE	Evolut™ EXPAND TAVR II Pivotal Trial
Official Title KOMJE	Evolut™ EXPAND TAVR II Pivotal Trial
Brief Summary	Obtain safety and effectiveness data to support indication expansion for the Medtronic TAVR System to include patients with moderate, symptomatic AS.
Detailed Description	Multi-center, international, prospective, randomized study. Subjects will be randomized to either transcatheter aortic valve replacement (TAVR) with the Evolut PRO+ TAVR System, or Evolut FX System, and guideline-directed management (GDMT) or GDMT alone.
Study Type KOMJE	Interventional
Study Phase KOMJE	Not Applicable
Study Design KOMJE	Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment
Condition KOMJE	• Aortic Stenosis Symptomatic • Moderate Aortic Valve Stenosis
Intervention KOMJE	• Device: Medtronic Evolut PRO+ TAVR System, or Evolut FX TAVR System, and guideline-directed management and therapy (GDMT) ◦ Patients will have a Transcatheter Aortic Valve Replacement (TAVR) with either an Evolut PRO+ TAVR, or Evolut FX TAVR, heart valve, and given clinical site-determined guideline-directed management and therapy (GDMT).
Study Arms KOMJE	• Experimental: Medtronic Evolut PRO+, or Evolut FX,TAVR System, & guideline-directed management & therapy (GDMT) ◦ Medtronic Evolut PRO+ TAVR or Evolut FX TAVR Systems, & guideline-directed management & therapy ◦ Interventions: ▪ Device: Medtronic Evolut PRO+ TAVR System, or Evolut FX TAVR System, and guideline-directed management and therapy (GDMT) • No Intervention: Clinical site determined guideline-directed management and therapy (GDMT) alone ◦ Clinical site determined guideline-directed management and therapy (GDMT) alone
Publications *	Not provided

* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.

Recruitment Information

Recruitment Status KOMJE	Recruiting
Enrollment (Estimated) KOMJE **(Submitted: 2021-11-24)**	650
Original Enrollment (Estimated) KOMJE	Same as current
Study Start Date (Actual) KOMJE	2022-04-27
Primary Completion Date (Estimated)	2026-02 (Final data collection date for primary outcome measure)
Study Completion Date (Estimated) KOMJE	2034-12
Eligibility Criteria KOMJE	Key Inclusion Criteria: • Moderate AS, defined as follows by transthoracic echo (TTE) at rest: ◦ Max aortic velocity ≥ 3.0 m/sec and < 4.0 m/sec, and ◦ Mean aortic gradient ≥ 20.0 mmHg and < 40.0 mmHg, and ◦ AVA >1.0 cm2 and < 1.5 cm2 • NYHA class ≥ II and symptoms of AS, including but not limited to: ◦ Dyspnea at rest or on exertion ◦ Fatigue ◦ Angina ◦ Syncope in the absence of another identifiable cause • LVEF > 20% by 2-D echo • Any of the following ◦ HF event or hospitalization for heart failure within 1 calendar year prior to qualifying echo ◦ NT proBNP ≥ 600 pg/ml (or BNP 80 pg/ml) measured within 6 months prior to or within 2 weeks after qualifying echo, ◦ Global longitudinal strain ≤15% (absolute value) at qualifying echo, or ◦ E/e' (average of medial and lateral velocities) ≥ 14.0 at qualifying echo Key Exclusion Criteria: • Age < 65 years • Class I indication for cardiac surgery • Sievers Type 0 or Type 2 bicuspid aortic valve or Sievers Type 1 bicuspid aortic valve with ascending aorta diameter > 4.5 cm • Not anatomically suitable for transfemoral TAVR with the trial device • In need of and suitable for coronary revascularization per Heart Valve Team • Documented history of cardiac amyloidosis
Sex/Gender KOMJE	Sexes Eligible for the Study: All
Ages KOMJE	65 Years and older (Older Adult)
Accepts Healthy Volunteers KOMJE	No
Location Countries KOMJE	Australia, Austria, Belgium, Canada, Denmark, France, Germany, Israel, Italy, Japan, Netherlands, Spain, Switzerland, United Kingdom, United States
Removed Location Countries	

Administrative Information

NCT Number KOMJE	NCT05149755
Other Study ID Numbers KOMJE	D00411092
Has Data Monitoring Committee	Yes
U.S. FDA-regulated Product	Studies a U.S. FDA-regulated Drug Product: No Studies a U.S. FDA-regulated Device Product: Yes Device product not approved or cleared by U.S. FDA: Yes
IPD Sharing Statement KOMJE	Plan to Share IPD: No
Current Responsible Party	Medtronic Cardiovascular
Original Responsible Party	Same as current
Current Study Sponsor KOMJE	Medtronic Cardiovascular
Original Study Sponsor KOMJE	Same as current
Collaborators KOMJE	Not provided
Investigators KOMJE	Principal Investigator: Paul Sorajja, MD — Allina Health System Principal Investigator: Josep Rodes-Cabau, MD — Fondation IUCPQ Principal Investigator: Stephan Windecker, Prof. — Inselspital, Universitätsspital Bern
PRS Account	Medtronic Cardiovascular

KOMJE Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP