EHRA-PATHS: Addressing multimorbidity in elderly atrial fibrillation patients through interdisciplinary, patient-centred systematic care pathways;Clinical and health economic evaluation of new care pathways

Published: 21-11-2023
Last updated: 25-03-2025

The aim of this study is to evaluate current management, implement new care pathways and evaluate if this leads to improved identification of risk factors and comorbidities and treatment initiation in multimorbid, elderly AF patients as compared to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON56435

Source
ToetsingOnline

Brief title
EHRA-PATHS

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: EU grant

Intervention

Keyword: atrial fibrillation, care pathways, multimorbidity

Outcome measures

Primary outcome

Primary Objective

To evaluate the management (assessment and treatment) of comorbidities in patients newly diagnosed with AF (Part 1) and to assess whether systematic implementation of new care pathways, including an easy-to-use software tool, improves the identification of AF associated risk factors and comorbidities and increases treatment initiation in elderly patients newly diagnosed with AF (Part 2).

Secondary outcome

Secondary Objective(s)

To evaluate possible differences between the intervention and control group in terms of:

• AF symptom burden

• Quality of life

• Referrals to other disciplines

• Patient and HCP satisfaction

• Cost-utility analysis

Study description

Background summary

The EHRA-PATHS consortium set out to address the need for change in management for multimorbid, elderly AF patients in Europe. The project aims to transform the current single-disease-focused pathway to holistic, inclusive and personalized treatment pathways, with the purpose of reducing personal, societal and economic burden compared to current standard of care. In order to do this, the consortium has characterized multimorbidity in elderly AF patients through databases and identified unmet needs within current clinical practice. Based on this information, new AF care pathways have been developed.

Study objective

The aim of this study is to evaluate current management, implement new care pathways and evaluate if this leads to improved identification of risk factors and comorbidities and treatment initiation in multimorbid, elderly AF patients as compared to current standard care.

Study design

The study consist of two parts;
• Part 1 - Observational (base mapping)
• Part 2 - Prospective, multicenter, international cluster randomized controlled trial

Patients will be included in Part 1 of the study, in which the current practice in the selected centres is observed; this will serve as base mapping of the current clinical practice.
Before the start of Part 2, centres randomized to the intervention group will receive dedicated training, either online or on-site. They also will have a run-in period to get acquainted with the EHRA-PATHS* new software tool. New AF patients in an intervention centre will receive a dedicated and personalized *risk factors and comorbidities evaluation and management plan*. The newly developed software tool will assist HCPs in providing this care.

Intervention

EHRA-PATHS* newly developed care pathways implemented in a software tool (Part 2).

Study burden and risks

Study participants will have three study visits in both study arms. Each visit

is expected to take 40 minutes. The first visit will take place in Part 1 and will consist of base mapping. Information on comorbidities and risk factors will be collected, depending on the current practice. In Part 2, the centres will be randomized to either intervention or control. Another two visits will take place during this part, in which the intervention group will follow the EHRA-PATHS* care pathways and the control group will continue the current local practice. In addition, questionnaires will be taken around the second and last visit in both groups. Extra visits are allowed in both groups, if deemed necessary by the HCP in order to optimize AF and/or comorbidity management. No harm is expected for this study as the intervention will be based on international guidelines. All patients will at least receive the standard care.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

* Newly diagnosed AF (paroxysmal, persistent or permanent)
* >=65 years of age
* Willing and able to participate and to attend the scheduled follow-up visits.

Exclusion criteria

* AF episode was due to a trigger (i.e. postoperative, infection, hyperthyroidism etc.)
* Life expectancy of less than 1 year
* Participation in another clinical study (registry studies not included)
* Severe cognitive impairment / dementia (defined based on MMSE and CDR scoring systems)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-04-2024
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	EHRA-PATHS software tool
Registration:	No

Ethics review

Approved WMO Date:	21-11-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-02-2025
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05773768
CCMO	NL83890.042.23