

# Observational data can aid decision-making about implantable cardiac monitors when RCT evidence is limited

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## Context

**Atrial fibrillation (AF)** is a heart arrhythmia that is a known risk factor for stroke. People who have had a stroke usually have at least 24 hours of external ECG monitoring to test for AF so treatment can be given to lessen the risk of further stroke. However, intermittent AF may be missed by standard ECG monitoring.

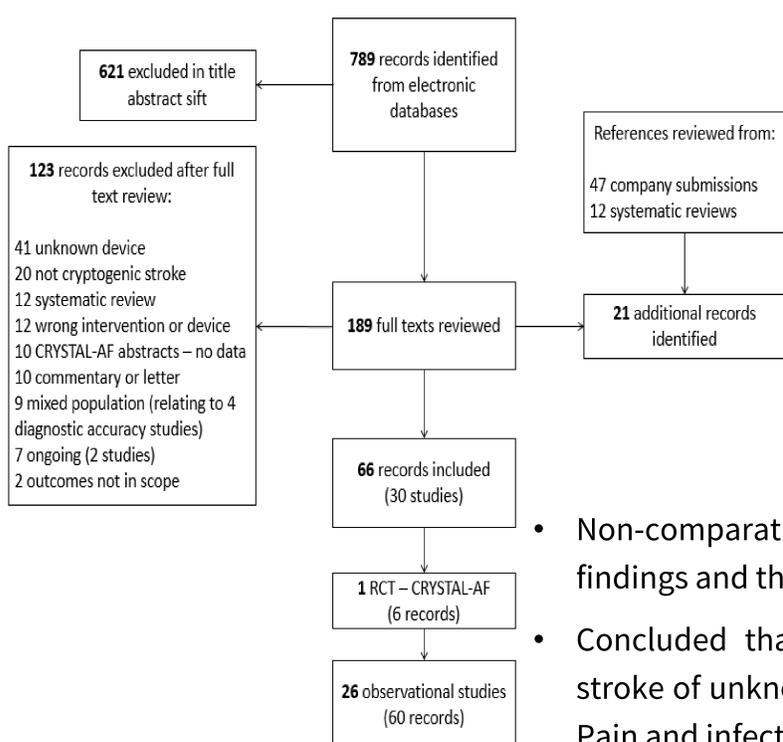
**Implantable cardiac monitors (ICMs)** are small recording devices that can be inserted under the skin of the chest. ICMs offer the possibility of much longer-term monitoring to detect AF in people for whom no known cause of stroke has been found.

**Who?** Patients with stroke of unknown cause and no AF after 24 hours of ECG monitoring

**What?** ICM (BioMonitor 2-AF™, Confirm RX™ or Reveal LINQ™) vs no further AF monitoring

**How?** A comprehensive systematic review of RCTs following Cochrane methodology to assess diagnostic test accuracy (DTA) and longer-term outcomes (e.g. stroke prevention)

## Key Results



- **One high quality RCT** found about an older Reveal LINQ device (CRYSTAL-AF; n = 441).
- Database searches were expanded to non-comparative studies to aid decision-making.
- No relevant RCT or non-comparative evidence was found for BioMonitor 2-AF or Confirm RX.
- 26 non-comparative studies assessing the current and older Reveal LINQ device (n=3,414) were identified and summarized alongside results of CRYSTAL-AF.
- Non-comparative results **improved the confidence** in the RCT findings and their generalizability to clinical practice.
- Concluded that **ICMs detect more AF than usual care** after stroke of unknown cause, but longer-term benefits are unproven. Pain and infection related to the devices are rare.

## BMJ TAG

### LESSONS LEARNED

Pragmatic decisions to amend a systematic review protocol are sometimes required to inform decision-making but changes should be stated explicitly. Non-comparative observational evidence can aid answering review questions where RCT data are sparse.

### PATIENT INVOLVEMENT

This research was initiated by the National Institute for Health and Care Excellence (NICE), which included patient representation from national patient groups in the preparation of the scope of the project.



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Implantable cardiac monitors (BioMonitor 2-AF, Confirm Rx insertable cardiac monitor and Reveal LINQ Insertable Cardiac Monitoring System) to detect atrial fibrillation after cryptogenic stroke: A Diagnostic Assessment Report

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