

# Transient Electrocardiogram Assessment in Stroke Evaluation (TEASE) – rationale and design: a prospective observational study using chest and thumb-ECG

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## Summary

**A prospective observational study with the aim to determine incidence of newly diagnosed atrial fibrillation in patients with cryptogenic stroke undergoing chest and thumb-ECG.**

Atrial fibrillation (AF) is a common cause of ischemic stroke. Detection of AF affect treatment. In this study, 100 consecutive patients diagnosed with cryptogenic stroke after usual care with 24-hour continuous ECG registration will be included (per protocol). Study participants will be screened for AF during 28 days, with chest and thumb-ECG twice daily and at symptoms. Through a smart phone application ECG will be manually interpreted daily by the researchers. After six weeks, study participants will report their experience using the system through a questionnaire. Health related quality of life (HRQoL) will be rated (SF-36) at week six and at twelve months.

**Background** In stroke patients with atrial fibrillation (AF), treatment with an anticoagulant is recommended instead of antiplatelet therapy, detection of AF thus affect treatment.<sup>1,2</sup> Episodes of AF are often not recognized or reported by the patient but are still associated with risk of stroke.<sup>3</sup> Possibilities for AF detection include repeated or continuous ECG, Holter monitoring, and external or insertable cardiac monitors.<sup>2</sup> An insertable cardiac monitor detected AF in 12.4% of cryptogenic stroke patients after one year.<sup>4</sup> Prolonged Holter monitoring for 7 days in stroke patients presenting with sinus rhythm detected AF in 12.5% compared with only 4.8% after 24-hours.<sup>5</sup> Thumb-ECG could offer a convenient and cost-effective method of screening.<sup>6</sup> A retrospective Swedish study found thumb-ECG superior to 48-hours Holter in stroke patients.<sup>7</sup>

**Aim** The primary objective is to assess the incidence of newly diagnosed AF during 28 days of chest and thumb-ECG in patients with cryptogenic stroke.

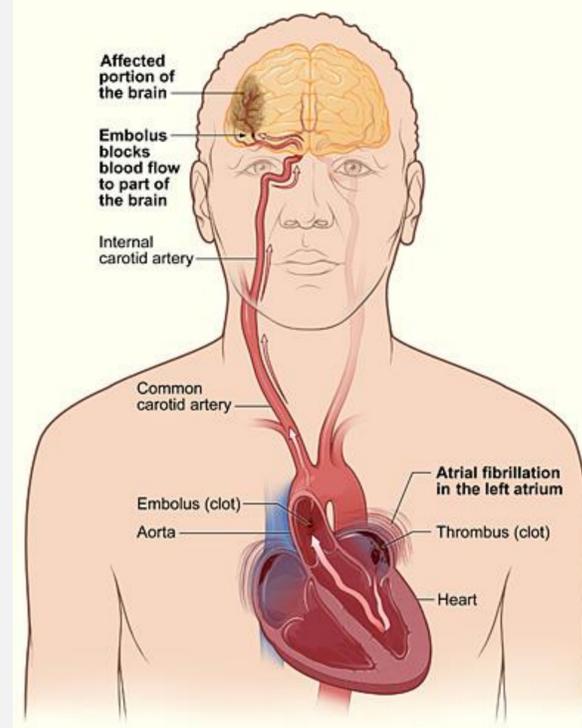
The secondary objective is to assesses feasibility of the Coala Heart Monitor™ in patients with stroke and determine HRQoL using SF-36.

**Outcomes** *Primary end-point:* 28 days cumulative incidence of AF. *Secondary end-points:* compliance at week four (number of recorded scheduled ECG tracings), patient reported experience of the chest and thumb-ECG measured at week six (self-developed questionnaire), HRQoL (SF-36) at week six and at twelve months.

**Method** *Setting:* 100 consecutive patients aged ≥18 years with cryptogenic stroke in Region Gävleborg.

*Exclusion criteria:* Previous permanent indication for anticoagulant therapy, pregnancy, cardiac device, life expectancy ≤6 months.

*Procedure:* Screening with Coala Heart Monitor™ (system for chest and thumb-ECG) during 28 days with scheduled recordings in the morning and evening, and patient activated recordings upon symptoms.



Source: National Heart, Lung, and Blood Institute; National Institutes of Health; U.S. Department of Health and Human Services.

AF may lead to the formation of thrombi, which may cause systemic embolization or ischemic stroke. AF increase the risk of stroke depending on risk factors (CHA2DS2-VASc).<sup>2</sup>

There is effective treatment in the form of anticoagulation. Warfarin reduce the risk of stroke by two thirds, non-vitamin K antagonist oral anticoagulants (NOACs) have proven even more effective and should be the first choice.<sup>8</sup>

Antiplatelet therapy is not recommended for stroke prophylaxis in AF. However, acetylsalicylic acid is the usual treatment in cryptogenic stroke. Thus, the detection of AF in stroke patients affect treatment and outcome.<sup>2</sup>

**Cryptogenic stroke** is a diagnosis made by ruling out known causes of stroke like carotid artery stenosis or AF. However, AF is often asymptomatic and paroxysmal, as such it is often not detected. In a study using an insertable cardiac monitor AF was detected in 12.4% of cryptogenic stroke patients after 12 months.<sup>4</sup>

**References**



**Questionnaire**



**SF-36**



An article on the study design and rationale will be published online under open access and will then be added to references.

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