DOAC Dipstick Testing in Acute Stroke: Multicentre Registry Protocol in Regional Australia

Summary of an Article | BMJ Open 2025 | Callaly EP, Tan PS, Schembri E, et al.

Why this paper matters to Haemoview Customers

This protocol addresses a high-stakes clinical problem: patients with acute ischaemic stroke or intracerebral haemorrhage who may have taken a direct oral anticoagulant (DOAC) shortly before presentation. In these settings, treatment decisions about thrombolysis or anticoagulant reversal are time-critical, but standard plasma DOAC assays can be slow or unavailable outside tertiary centres.

The study evaluates whether a rapid urine-based point-of-care test, DOASENSE, can help identify clinically significant DOAC exposure across regional hospitals in Victoria and Tasmania. For Haemoview customers involved in coagulation testing, stroke pathways and urgent bleeding management, the paper is relevant because it focuses on faster triage, decentralised testing and more targeted escalation of therapy.

Study at a glance

Item	Detail
Article type	Protocol for a multicentre, prospective, observational registry study.
Journal	BMJ Open 2025;15:e102092.
Setting	Hospitals across Victoria and Tasmania, focused on the Victorian Stroke Telemedicine service catchment.
Population	Adults with suspected acute ischaemic stroke, transient ischaemic attack or radiologically proven intracerebral haemorrhage, with apixaban, rivaroxaban or dabigatran ingestion within 48 hours.
Intervention under evaluation	Rapid urine DOAC dipstick testing with visual interpretation and, where available, the DOASENSE reader.
Comparator	Plasma DOAC concentrations measured by chromogenic assays.
Target sample size	146 participants, powered for agreement analysis using the kappa statistic.

Key message: This is not an outcomes trial of thrombolysis or reversal therapy. It is a real-world registry protocol designed to test whether rapid urine DOAC screening can reliably support acute stroke decision-making when plasma assays are slow, centralised or unavailable.

Source: Callaly EP, Tan PS, Schembri E, et al. Evaluating DOAC dipstick testing in the management of acute stroke: protocol for a multicentre, prospective, observational registry study. BMJ Open. 2025;15:e102092. doi:10.1136/bmjopen-2025-102092.

Clinical problem the protocol addresses

Current stroke guidelines caution against intravenous thrombolysis in anticoagulated patients, yet some patients who appear to be anticoagulated may actually have low or off-therapy plasma DOAC levels. Those patients may still be candidates for reperfusion therapy if clinically appropriate and if significant DOAC exposure can be excluded quickly.

The protocol also addresses intracerebral haemorrhage, where rapid assessment of DOAC exposure may influence decisions about pharmacological reversal. Because reversal agents can be costly, limited in availability and associated with risk, the paper highlights the value of better selection rather than empiric treatment.

What the study will measure

Outcome group	Measures
Primary outcomes	(1) Proportion of acute ischaemic stroke participants with off-therapy plasma DOAC levels; (2) proportion found eligible for reperfusion therapy because of plasma DOAC level and DOASENSE testing.
Secondary outcomes	Stroke aetiology by TOAST classification, plasma levels and DOASENSE results in DOAC-associated intracerebral haemorrhage, false-negative and false-positive dipstick results at a clinically significant plasma threshold of 30 ng/mL or more, and exploratory analysis of false negatives.
Accuracy analyses	Kappa agreement, sensitivity, specificity, positive predictive value and negative predictive value of DOASENSE against dichotomised plasma concentrations.

Why the design matters

- Prospective registry design supports structured real-world data collection across multiple centres.
- Regional Australian participation improves relevance beyond tertiary metropolitan laboratories.
- Comparison with laboratory plasma assays gives the study a practical validation framework.
- Inclusion of both ischaemic stroke and intracerebral haemorrhage broadens clinical utility.

Relevance to haemostasis and stroke pathways

This study sits at the intersection of acute stroke triage, anticoagulant assessment and decentralised coagulation diagnostics. Its core question is whether rapid urine DOAC screening can add clinically useful information early enough to affect urgent treatment pathways in hospitals that may not have immediate access to plasma assays.

Protocol feature	Practical relevance
Urine dipstick result available within minutes	Supports faster front-end decision-making when thrombolysis eligibility or reversal need must be assessed rapidly.
Regional and telemedicine-connected sites	Relevant to hospitals without on-site specialist coagulation testing or tertiary stroke laboratory infrastructure.
Threshold-based classification of plasma DOAC levels	Aligns with practical rule-in/rule-out thinking around clinically significant drug exposure.
Visual reading plus reader-based analysis	Important for workflow discussions about standardisation, training and implementation variability.

Suggested conversation points

- “This protocol is designed to test whether rapid urine DOAC screening can support acute stroke decision-making in hospitals where plasma assays may be too slow or unavailable.”
- “The study is especially relevant to regional stroke pathways, because it looks at real-world implementation across Victoria and Tasmania rather than only a single tertiary centre.”
- “The key question is not just analytical agreement, but whether rapid DOAC status assessment changes who becomes eligible for reperfusion therapy or targeted reversal.”
- “The protocol also recognises the operational issue that reversal agents are costly and limited, so better triage may matter as much as better detection.”

Sources

Callaly EP, Tan PS, Schembri E, et al. Evaluating DOAC dipstick testing in the management of acute stroke: protocol for a multicentre, prospective, observational registry study. BMJ Open. 2025;15:e102092. doi:10.1136/bmjopen-2025-102092.

Key Takeaway

This multicentre registry protocol will test whether rapid urine DOAC dipstick screening can reliably identify clinically relevant anticoagulant exposure in acute stroke and support faster treatment triage.

Why it matters

Timely thrombolysis and targeted reversal decisions depend on knowing whether a patient has clinically significant DOAC levels, yet plasma assays may be delayed or unavailable outside tertiary centres.

Clinical Insight

The study is focused on practical implementation in regional stroke networks, where point-of-care rule-out strategies may have the greatest effect on access to reperfusion decisions.

Impact

If agreement with plasma testing is strong, rapid urine DOAC assessment could support decentralised stroke care, more targeted use of reversal agents and faster escalation to definitive treatment.

Future research ideas

Once registry data are available, the next step will be to determine whether rapid DOAC dipstick testing changes time-to-treatment, thrombolysis access, reversal-agent use and downstream clinical outcomes in routine care. Further work may also need to refine reader thresholds, reduce invalid sample rates and understand how renal impairment, urine quality and sampling conditions influence test performance.

Source: Callaly EP, Tan PS, Schembri E, et al. BMJ Open. 2025;15:e102092. doi:10.1136/bmjopen-2025-102092.

Protocol snapshot

Domain	Details
Design	Multicentre, prospective, observational registry led by Eastern Health.
Participants	Adults over 18 with suspected acute ischaemic stroke, transient ischaemic attack or proven intracerebral haemorrhage and recent DOAC ingestion within 48 hours.
Drugs covered	Apixaban, rivaroxaban and dabigatran; if the specific DOAC is unknown initially, plasma testing for all three may be performed.
Testing workflow	Urine dipstick interpreted visually by a trained observer, photographed for quality control, and analysed with a DOASENSE reader where available.
Invalid samples	Samples with abnormal urine colour or low urine creatinine are considered unreliable and excluded from final analysis.
Statistics	Kappa agreement, sensitivity, specificity, predictive values, and comparison of reperfusion eligibility by DOASENSE vs plasma testing.

Important limitations flagged by the protocol

- Dipstick interpretation may vary because visual reading remains part of the workflow.
- Stroke aetiology classification may be limited where later outpatient investigations are unavailable.
- The protocol evaluates diagnostic and pathway utility, not definitive treatment efficacy.
- Because clinicians are not blinded to dipstick results, management decisions will reflect real-world practice rather than a controlled intervention design.

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STUDY PROTOCOL

DOAC Dipstick Testing in Acute Stroke

Multicentre Registry Protocol in Regional Australia

Can rapid urine DOAC screening help guide thrombolysis and targeted reversal when time is critical?

Based on Callaly EP, Tan PS, Schembri E, et al. *BMJ Open* 2025;15:e102092

WHY THIS MATTERS

Patients on direct oral anticoagulants (DOACs) may be excluded from urgent stroke treatments if clinically significant drug levels cannot be ruled out quickly.

Standard plasma DOAC assays may be slow or unavailable outside tertiary centres.

Rapid point-of-care urine screening could support faster triage, reperfusion decisions, and targeted reversal.

Faster triage | **Support thrombolysis decisions** | **Guide targeted reversal**

THE SCIENCE STORY: HOW THE PROTOCOL WORKS

1. **CLINICAL PROBLEM**
   Acute ischaemic stroke or intracerebral haemorrhage in patients with recent DOAC use.
2. **INDEX TEST**
   DOASENSE urine dipstick with visual interpretation and, where available, reader-based analysis.
3. **REFERENCE TEST**
   Plasma DOAC concentration measured by chromogenic assays.
4. **WHAT THE REGISTRY ASKS**
   Does rapid urine testing agree with plasma testing and help identify who may be eligible for reperfusion therapy or pharmacological reversal?

3 KEY POINTS

1 A REAL-WORLD REGIONAL STUDY

Multicentre prospective observational registry across Victoria and Tasmania, designed to reflect regional stroke pathways and telemedicine-connected care.

2 RAPID URINE TEST VS PLASMA ASSAY

Adults with suspected acute ischaemic stroke, TIA, or intracerebral haemorrhage and recent apixaban, rivaroxaban, or dabigatran use will undergo DOASENSE urine testing compared with chromogenic plasma DOAC assays.

3 THE STUDY IS ABOUT DIAGNOSTIC AND PATHWAY UTILITY

Primary outcomes include the proportion of ischaemic stroke patients with off-therapy plasma DOAC levels and the proportion found eligible for reperfusion therapy based on DOASENSE and plasma DOAC testing.

Target sample size: 146 participants.

WHAT WILL BE MEASURED?

AGREEMENT METRICS
kappa

DIAGNOSTIC PERFORMANCE
sensitivity, specificity, PPV, NPV

SECONDARY OUTCOMES
Stroke aetiology, DOAC-associated intracerebral haemorrhage, false negatives/false positives at ≥30 ng/mL, and factors contributing to false negatives.

CLINICIAN TAKEAWAY

This is a protocol, not a treatment-outcomes trial. If agreement with plasma testing is strong, rapid urine DOAC screening could support faster decision-making in acute stroke pathways, especially in regional hospitals where plasma assays are delayed or unavailable.

IDEAS FOR FURTHER RESEARCH

- Does rapid screening shorten time-to-treatment or expand thrombolysis access?
- Can it improve targeted use of reversal agents in intracerebral haemorrhage?
- How do renal impairment, urine quality, and sampling conditions affect performance?

IMPORTANT LIMITATIONS

- Visual interpretation may introduce variability.
- Invalid samples with abnormal urine colour or low urine creatinine are excluded from final analysis.
- The protocol evaluates implementation and diagnostic utility, not definitive treatment efficacy.

BOTTOM LINE: This registry will test whether rapid urine DOAC dipstick screening can help acute stroke teams make faster, better-informed triage decisions when plasma testing is slow or unavailable.

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Created by Haemoview Diagnostics. Based on Callaly EP, Tan PS, Schembri E, et al. Evaluating DOAC dipstick testing in the management of acute stroke: protocol for a multicentre, prospective, observational registry study. *BMJ Open* 2025;15:e102092.
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