

PB-PG-1207-15216 – NIHR Research for Patient Benefit Programme – Final report

Project title: RAPid Primary care Initiation of Drug treatment for TIA (RAPID-TIA) – a pilot trial

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Plain language summary

Transient ischaemic attacks (TIA) are like having a stroke, except the symptoms wear off. It is important that people who have a TIA are treated promptly because they are at high risk of going on to have a stroke and there are treatments which can greatly reduce this risk.

Current guidelines recommend that people with a TIA are seen as soon as possible by a specialist to establish the diagnosis and initiate treatment. An alternative approach would be for the GP to start treatment before the patient sees the specialist. We wanted to carry out a clinical trial comparing GP initiation of treatment to standard practice, but before we could do this trial we needed to do some preliminary work, which is the focus of this research.

Our literature review found little information available to assess how GPs diagnose TIA with methodological flaws in existing studies and so it was not possible to use an evidence based tool to improve referral decisions.

Our interviews with GPs and people who had had TIA provided us with a number of practical pointers as to how to conduct the trial. They also provided us with information on how GPs use rules to guide referral, which has implications outside the management of TIA.

We carried out a pilot trial in which we recruited 30 practices, but over the course of a year only 16 patients were recruited to the study. We had expected 167 patients. The main problem was that patients presenting with TIA were not identified in a timely fashion. Also, practices struggled to meet the practical issues of recruiting participants in the context of an emergency consultation.

Only 4 of 10 patients that the GPs thought had had a TIA had really had one.

We conducted an audit to understand why so few patients had been recruited. 332 TIA like events occurred in patients registered with the general practice, which is consistent with what we had expected. However, the vast majority of these were not identified as being potentially eligible for the study until it was too late. Furthermore, most of the patients that were identified in time were not recruited, most commonly because of practical reasons (e.g. time pressure).

In conclusion, while it appears feasible from our qualitative research for GPs to initiate treatment for TIA, it is not possible to perform a randomised controlled trial to test this strategy. Other approaches will need to be pursued (e.g. mathematical modelling) to determine whether or not GP initiation is worthwhile.

Keywords

Transient Ischaemic Attack; TIA; Primary Care; Rapid Access TIA Clinics

Summary of research findings

Background

People who have a transient ischaemic attack (TIA) or minor stroke are at high risk of a recurrent stroke, particularly in the first week after the event. The National Stroke Strategy recommends that people with a TIA are seen by a specialist urgently, and that secondary prevention drugs should be given as soon as the diagnosis is confirmed. Very early initiation of secondary prevention drugs may reduce stroke risk by 80%. This raises the question as to whether the drugs should be initiated in primary care before the patient has seen a specialist.

Aims and Objectives

Aim: To determine the feasibility of a randomised controlled trial comparing GP initiation of secondary prevention with standard practice (initiation by the specialist).

Objectives: To address the following questions:

1. What should be included in guidance to GPs on diagnosis of TIA?
2. What are patient and primary health care professional attitudes towards GP initiation of therapy and how consent should be obtained?
3. Is randomisation at individual patient level possible?
4. What is the recruitment rate of patients to the trial?
5. Are there any adverse events in patients who receive secondary prevention drugs prior to specialist diagnosis?
6. How accurate is GP diagnosis of TIA?

Methods

A literature review to address question one. A qualitative interview study of 14 participants (6 patients; 8 GPs) to address question 2. A pilot randomised controlled trial to address questions 3 to 6. We recruited 30 general practices from Birmingham, Oxfordshire and Cambridge and one A&E department (Addenbrooke's). When a primary care professional sees a patient with suspected TIA, they record whether they think TIA is probable or possible. All are referred to a specialist TIA clinic. Probable cases are invited to enter the pilot trial, possible cases the study of accuracy of GP diagnosis. Patients are randomised by telephone, stratified by TIA clinic and stroke risk, to immediate initiation of treatment (plus referral) or referral alone. The TIA clinic will record final diagnosis and adjust treatment accordingly. The primary outcome is stroke at 90 days.

Due to poor recruitment to the trial, we conducted an additional audit to seek to understand the reasons for this.

Key findings

Systematic review: Limited data is available to assess how GPs diagnose TIA with methodological flaws in existing studies from use of artificial cases, non-randomisation of case order on questionnaires, cueing as to the potential for a TIA diagnosis and restriction to anterior circulation syndromes. Excluding posterior circulation presentations is not logical as the risk of recurrent stroke is as high as after anterior circulation events. Recognition tools are well developed for stroke but not for TIA, and none are based on primary care recorded data and consequently a tool to improve referral decisions does not yet exist.

Qualitative study: immediate initiation of treatments was not current practice for the GPs who were interviewed, but there was acceptance that if it was justified, they would do it. Practical constraints were a concern, and strategies to overcome these were suggested (ask patients back at the end of surgery; use a lead GP; delegation to other health care professionals). Some patients were concerned about drugs being started without a firm diagnosis, and whether it was right for a non-specialist to do this. GPs expressed that they might have a preference for a particular patient as to whether or not drugs should be started, and likewise some patients expressed a preference as to which treatment they would want. These issues informed the patient information sheet. We also asked both primary care and secondary care professionals about how they use the ABCD2 score (the clinical prediction score which is recommended to determine how urgently patients with suspected TIAs should be referred). We found that the score is used in multiple ways beyond its original evidence based purpose of risk stratification. Despite (or because) of this, the score successfully facilitates communication across clinical domains.

Pilot randomised controlled trial: over one year, 11 patients with probable TIA were randomised to the trial (3 from A&E) and an additional 5 patients (3 from A&E) with possible TIA entered the diagnostic study. 5 were randomised to the intervention group and 6 to the control group. There were no significant adverse events in trial participants, and by 90 day follow up no primary events had occurred, and only one secondary event (cardiac chest pain in a control patient who had not had a TIA).

Diagnostic accuracy study: Final diagnosis was obtained for 10 of the 11 randomised patients. Only 4 out of 10 (PPV 40%) had TIA confirmed by the specialist. The rest had: cervical root impingement; sciatic nerve palsy; transient global amnesia; atrial fibrillation; faint; and dehydration. Of the 5 'possible' TIAs, one was diagnosed by the specialist as having TIA.

Audit study: 322 potential TIAs were identified from searching the GP computers systems for the relevant time period of the study – i.e. 12 potential cases per practice per year. In 18 practices, only 42 out of 227 (18%) potential TIAs were identified in a timely fashion (i.e. could have been recruited into the trial). Of these, 9 met one of the exclusion criteria for the trial, 3 had already been seen at the hospital, 12 were not randomised because of practical reasons (e.g. lack of time), 5 patients did not want to take part.

Expected impact: We have demonstrated that it is not feasible to conduct a randomised controlled trial to answer the question as to whether or not GPs should initiate secondary prevention treatment in people with suspected TIA. We have found that there is insufficient evidence available to guide GPs on how to diagnose TIAs. While the numbers in our study were small, the positive predictive value of GP diagnosis of only 40% is consistent with the literature, and suggests that if GPs are to initiate treatment, then research to inform guidance for GPs on diagnosis is warranted.

Conclusions

In conclusion, while it appears feasible from our qualitative research for GPs to initiate treatment for TIA, it is not possible to perform a randomised controlled trial to test this strategy. Other approaches will need to be pursued (e.g. mathematical modelling) to determine whether or not GP initiation is worthwhile.

Patient and public involvement

We have two people on the team who provide the PPI for this study: PPI co-applicant 1 and PPI co-applicant 2. PPI co-applicant 1 is also a co-applicant on this grant. Both patients were representatives on the Trial Steering Committee (TSC) and played an active role in guiding the progress of the research. When the recruitment rate was discussed at the TSC meetings, the PPI advice was invaluable. They advised that, despite recruitment problems, the question was still a valid and important one, because prevention of stroke is an important area of interest for patients. This contributed directly to the teams decision to increase the focus on recruitment methods and audit because it was felt that determining the feasibility of a full trial would be better considered if good and poor recruitment approaches were identified. They were involved in the development of the interview schedule for the qualitative element of the project to ensure that the schedule allowed for discussion of all areas that were likely to be of relevance or importance to patients. Both PPI members also extensively reviewed all study paperwork, including information sheets and data collection forms, and commented constructively on their content and suitability for purpose.

It was decided not to hold any patient forums or focus groups to gain further PPI advice for the design of this particular study because it was felt that to do so would be duplicating some of the research itself. The design of the interview element of the project was guided by PPI input, as explained above, and one of the aims of this section of the research was to determine patient thoughts about the acceptability and design of the RCT element.: the interview findings were used to inform the design of the pilot trial. Therefore, there was no additional benefit to be gained from further PPI involvement at this stage.

PPI co-applicant 1 was directly involved with the publication of the protocol paper and the qualitative study results and his input and comments, especially in the qualitative paper enabled us to draw conclusions that are relevant to the interests of patients.

The experience of this team with regard to PPI involvement was overwhelmingly positive. They contributed to and guided design and progress in a way that enabled us to maximise the potential of the project and to ensure it remained relevant to patient interests.

Data sharing statement

See link

[\[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253\]](https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253) for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

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This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.

This project was carried out between January 2010 and December 2012.