TARDIS – Working Practice Document No: 004

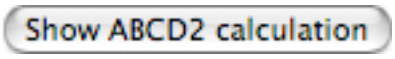
Title: Completion of Baseline Form

Baseline data is collected prior to randomisation, within 48 hours of the time of stroke onset and after written patient (relative/independent physician) consent obtained, by an appropriate investigator already authorised on the signature/delegation log.

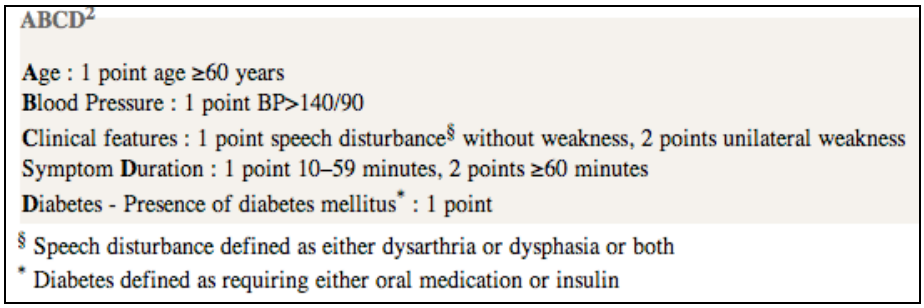
1. Logon to the TARDIS website (http://www.tardistrial.org) and open the 'Add new patient' page.

2. Read through the list of inclusion and exclusion criteria and check that the identified patient fulfils all of these.

3. If you need help in calculating the ABCD2 score, then click on the:



button and the following will be displayed



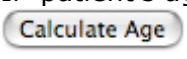
4. If any of the criteria are not fulfilled do not continue further, do not try to randomise this patient.

5. If the patient fulfils the inclusion and exclusion criteria choose 'YES enrol' to continue, otherwise 'No' to return to previous screen, or 'Logoff' to exit the Trial database.

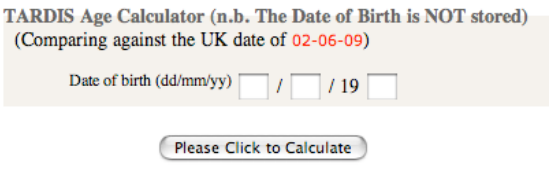
PATIENT DETAILS

6. Enter patient's initials (max 3 characters). If no middle name then just enter 2 initials.

7. If patient's age is known, enter directly into the box. Otherwise click on the



button and the following is displayed:



Enter patient's date of birth, click on button to calculate. Then after closing down this help box, enter the result given against the Age field.

8. Click on either male or female.

9. Choose the appropriate ethnic group from the drop-down box.

10. Enter the patient's dominant hand if known, otherwise click on 'unknown'.

11. Choose whether or not the qualifying event is a TIA or Stroke. Some of the later entries will be validated against your answer to this question.

12. Select source of referral from the drop down box. Note:

    a. 'Hospital (inpatient)' should only be chosen if the qualifying event occurred whilst already an inpatient.

13. For the question 'Do you intend to admit the patient?' then choose:
    a. 'Yes' if the patient is admitted, or expected to be admitted for the qualifying event,
    b. 'No' if TIA and/or patient will not be admitted,
    c. 'N/A' if patient already in hospital when qualifying event occurred (as 12.a.above.

RANDOMISING/QUALIFYING EVENT DETAILS

14. Enter the date and time of randomisation attempt in the format dd/mmm/yyyy hh:mm,

15. Enter the date and time of stroke/TIA onset and duration of symptoms. (Stroke onset time is recorded as the last time the patient was seen well).

    a. For TIAs enter the actual length of symptoms in hours/minutes
    b. For STROKE then 'ONGOING' must be chosen and be applicable as patient must still have limb weakness or dysphasia at randomisation (see inclusion criteria).

16. The date and time of admission to hospital should be entered in the above format, if appropriate, otherwise leave blank. (Circle 'N/A' on paper form if not admitted)

17. Choose 'Yes' or 'No' depending whether the episode is diagnosed as a crescendo TIA (i.e. more than 1 TIA within the last week).

    a. If 'Yes' is chosen then enter the date of the last TIA before this qualifying event,
    b. and enter how many TIA have occurred within the last week (including the qualifying event).

RISK FACTORS / PAST MEDICAL HISTORY

18. Record any risk factors and enter details of previous medical history from the hospital notes or by asking the patient directly.

    If yes is entered for:

a. Atrial fibrillation,
b. MI or ACS within last 12 months,
c. major bleed within the last 12 months,
d. treated with tissue plasminogen activator (rt-PA) within 30hrs of onset of qualifying event

then the database will not allow this recruit to be randomized.

MEDICATIONS

19. In Sections D & E questions are asked about any of the following medications routinely prescribed and taken by the patient **prior** to this qualifying event:
    a. Antithrombotic
    b. Antihypertensive
    c. Lipid lowering
    d. Anti gastric acid

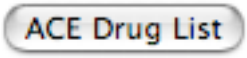
20. Antithrombotic medication
If a patient is currently taking asasantin, then please answer 'yes' for both aspirin and dipyridamole fields.

Patients are eligible if they have taken aspirin, dipyridamole or clopidogrel routinely prior to onset of the qualifying event, or on any dual but not triple combination.

However, if they have taken clopidogrel after onset of the qualifying event they will be rejected as they are no longer eligible to be randomised. Aspirin and/or dipyridamole may be taken after onset and before randomisation.

21. You will also be asked whether or not you plan to start or continue a PPI or H2 antagonist.

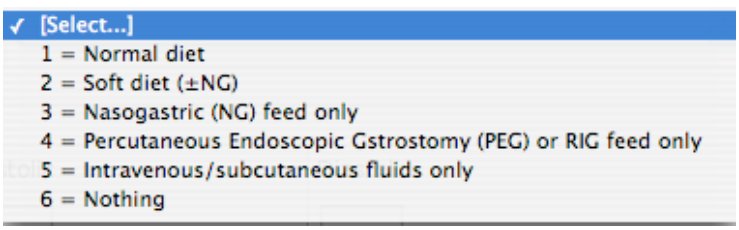
If you are unsure about any drug names, click on the drug list against the type of drug to view possible medications available. If the drug is not listed, then the selected answer should be either 'No' or 'Not Known'.

e.g 

Please note: Although we have made every effort to identify all current medications, we appreciate that this may change as new drugs are introduced and we would welcome any information if this is the case.

22. Enter Premorbid Modified Rankin Score – only 0, 1 or 2 is allowed. (see inclusion criteria)

23. Record the current feeding ability of the patient. If options 5 or 6 are chosen, this patient will not be randomized.



BASELINE HAEMODYNAMIC AND OTHER MEASURES

24. Two baseline blood pressure recordings are needed. Both systolic must be equal to or less than 185 and both diastolic must be equal to or less than 110, otherwise the patient cannot be randomized. Two heart rate readings should be taken at the same time.

    Note: If routine practice at your site is to treat the hypertension then this is allowed – and the patient can then be randomized if the blood pressure returns within the limits stated above, providing randomization can still be done within 48 hours of onset of the qualifying event.

25. The heart rhythm on the baseline ECG should be recorded. If the patient is in Atrial Fibrillation then randomization will not be allowed, as the event could be cardioembolic in origin. (see exclusion criteria)

26. Blood sugar readings are required. If only a BM test is done then this result will be adequate.

27. Baseline temperature and actual or estimated weight of the patient is also required.

GLASGOW COMA SCALE

28. Complete Glasgow Coma Scale – total must equal 8 or more to allow randomization of patient.

STROKE AND TIA DATA

29. Record the qualifying event presenting symptoms and whether they have resolved or are still present. Answer 'NO' if any symptoms were never present.

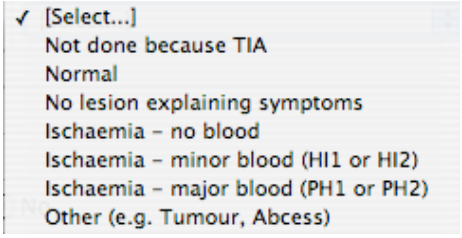
30. Also enter the side of patient's **<u>symptoms for this qualifying event only</u>**. Previous weakness through other causes should not be entered here.

31. Complete the NIHSS Score (enter total on the paper copy only*).*

BASELINE IMAGING DETAILS

32. Enter date and type of scan CT / MRI. 'No Scan' can only be accepted for TIAs who were not scanned after onset of symptoms and prior to randomization.

33. Then choose one of the following options with regard to the result of the baseline scan.



(See document – 'TARDIS scanresults.ppt' for help in completing the above)

If 'Ischaemia-major blood' or 'Other' are chosen, then the recruit will NOT be randomised as they will not be eligible (see exclusion criteria).

BLOODS

34. Enter details of which blood tests have been performed.

    a. Full Blood Count (mandatory)
    b. P-Selectin sub-study
    c. EDTA for genetic analysis (separate consent form required)
    d. Serum for freezing
    e. Plasma for freezing

    (SEE: Working Practice Documents '017-TARDISWPDpselectinbloods' and '029-TARDISWPDbloodcollectstore' for full details)

35. Baseline full blood count results must be entered here.
    These will be the clinical bloods taken between the qualifying event and prior to randomization, to ensure patient fulfils inclusion/exclusion criteria.

36. Select whether the patient is still eligible to enter the trial.

37. If you think all details are entered correctly, Enter your Investigator PIN and click on the 'next' button.

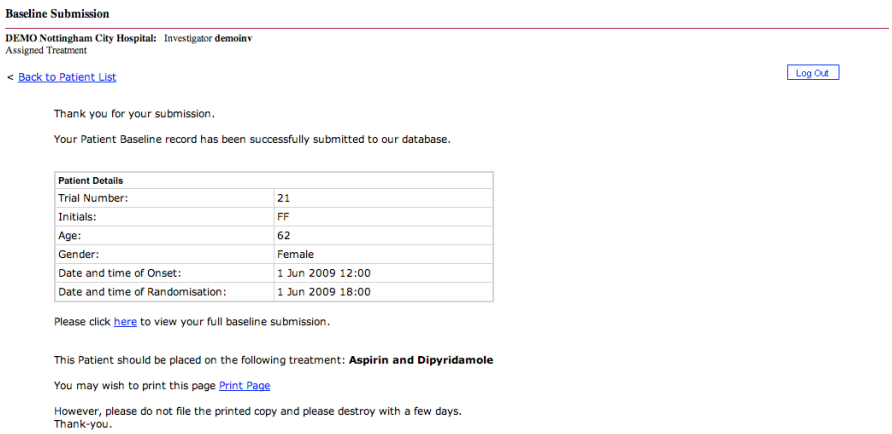
38. You will be re-directed back to the data entry page, with any omissions or errors identified in red.

    If any of the data entered is outside of the inclusion or exclusion criteria this will also be highlighted in red. You must re-check this to ensure the patient remains eligible for entry into the trial.

39. Re-enter any of the omitted/incorrectly entered data and then re-enter your PIN number.

40. You will be re-directed to the data entered and asked to check it again. If all is correct, re-enter your PIN number and submit the data.

41. The randomisation result will then be displayed on screen, as per the following example. This is the only time you will get to see the randomisation result so please ensure you write it down on the baseline paper form. If you require a printed copy, press the print button. If you misplace the randomisation result, please telephone the TARDIS Trial Office on 0115 823 0210.



Baseline Submission

DEMO Nottingham City Hospital: Investigator **demoinv**
Assigned Treatment

< Back to Patient List

Log Out

Thank you for your submission.

Your Patient Baseline record has been successfully submitted to our database.

Patient Details	
Trial Number:	21
Initials:	FF
Age:	62
Gender:	Female
Date and time of Onset:	1 Jun 2009 12:00
Date and time of Randomisation:	1 Jun 2009 18:00

Please click here to view your full baseline submission.

This Patient should be placed on the following treatment: **Aspirin and Dipyridamole**

You may wish to print this page Print Page

However, please do not file the printed copy and please destroy with a few days.
Thank-you.

42. If completing the paper CRF ensure the 'centre number, form submitted by and patients trial number' have been added. The paper CRF needs to be signed and dated at the end. Please then file the paper copy in the patients trial file record – or if done directly onto the database, file the printed results.

If following data submission you realise you have entered incorrect data on the website do not attempt to randomise the same patient twice. Please complete a 'data correction form' (copy on website for downloading) and fax this to the Co-ordinating Centre [+44 (0) 0115 8230273], where that data will be changed online.

Please be very careful when entering the data online and scrolling down between boxes, as this can change the data entered in the previous box, if you have not clicked out of it before-hand.

If you have any problems with the fax then please e-mail us at the TARDIS trial centre at tardis@nottingham.ac.uk or call on 0115 823 0210.

PLEASE NOTE:

The results of any assessments undertaken on the patient that are not routinely performed but are undertaken as part of TARDIS Trial, must be entered into the patient's medical records.