



## NEWSLETTER 6 – JANUARY 2008

HAPPY NEW YEAR AND HERE'S TO THE  
START OF A BUMPER **FINAL**  
RECRUITMENT YEAR!!!

**686** patients have been recruited to the TracMan trial at the time of going to press! TracMan is now the **largest** tracheostomy timing trial in the world! (.....but we need to get even larger!). Recruitment to the trial will finish in under 12 months time on 31<sup>st</sup> December 2008.



**This year, the following hospitals have recruited patients to the trial:**

Bedford Hospital  
Causeway Hospital  
City General, Stoke on Trent  
Derriford Hospital  
Dumfries & Galloway Royal Infirmary  
Eastbourne District General Hospital  
Freeman Hospital  
Glenfield Hospital  
Hairmyres Hospital  
Huddersfield Royal Infirmary  
Hull Royal Infirmary  
James Cook University Hospital  
James Paget Hospital  
John Radcliffe Hospital  
King George Hospital, Essex  
Kings College Hospital - Liver ICU  
Kings Mill Hospital  
Kingston Hospital

Leicester Royal Infirmary  
Luton & Dunstable Hospital  
Manchester RI – Cardiac ICU  
Manchester RI – General ICU  
Medway Maritime Hospital  
New Cross Hospital  
Peterborough District Hospital  
Princess Alexandra Hospital, Essex  
Queen Alexandra Hospital, Ports  
Royal Infirmary of Edinburgh  
Rochdale Infirmary  
Royal Alexandra Hospital, Paisley  
Royal Bournemouth Hospital  
Royal Cornwall Hospital  
Royal Devon & Exeter Hospital  
Royal Hampshire County Hospital  
Royal Surrey County Hospital  
Scunthorpe General Hospital

South Tyneside District General  
Southampton General Hospital  
St Richards Hospital, Chichester  
St Thomas' Hospital  
Stafford General Hospital  
Taunton & Somerset Hospital  
University College Hospital, London  
University Hospital Lewisham  
Weston General Hospital  
Whiston Hospital  
Whittington Hospital  
Worthing Hospital  
Wythenshawe Hospital  
Yeovil District General Hospital

**Thank You!!**

**There are some new hospitals that are in the process of joining the Trial and should be ready to recruit patients soon, this includes:**

Birmingham Heartlands  
Colchester General  
George Eliot Hospital

Newcastle General  
Royal Preston  
Royal Victoria, Belfast

## UNIT VISITS

Joanne and Linda are more than happy to visit units to talk on the trial and its background, and which forms to fill in when, to any size of audience.

They are also happy to visit and give small group teaching sessions in helping identify patients that should be entered into the trial.

Joanne and Linda can also visit your unit to help completing the trial data booklets to reduce any work burden imposed by the trial.

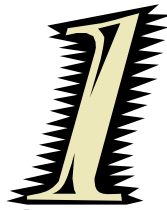
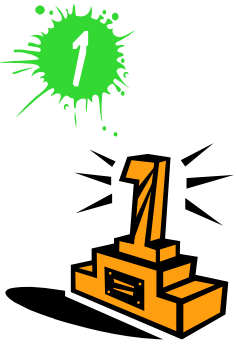
If you would like Jo or Linda to visit your unit, please email [TracMan@nda.ox.ac.uk](mailto:TracMan@nda.ox.ac.uk) or call 01865 857652.

Remember!

Just one!

1

If every ICU eligible to recruit patients to the trial recruited at least 1 patient each month to the trial, we could finish with over 1500 patients!!!!



## A REMINDER ON THE IMPLEMENTATION OF THE MENTAL CAPACITY ACT 2005 (implemented in 2007) for trial sites in ENGLAND AND WALES

How can a patient be entered into the TracMan Trial in England and Wales?

- Patient written consent
- Verbal Personal Consultee agreement (i.e. a friend or relative)
- Signed Personal Consultee agreement
- Signed Nominated Consultee agreement (i.e. a professional) (may not be available at all Trusts)



Once the Mental Capacity Act 2005 is implemented in Northern Ireland, hospitals in NI will follow the same consent processes as England and Wales, until then,

How can a patient be entered into the TracMan Trial in Northern Ireland?

- Patient written consent
- Signed 'No Objection' Form for Relative
- 'No Objection' Form Verbal

## ADULTS WITH INCAPACITY (SCOTLAND) ACT 2000 for trial sites in SCOTLAND

How can a patient be entered into the TracMan Trial in Scotland?

- Patient written consent
- Verbal Welfare Guardian/Nearest Relative Consent
- Signed Welfare Guardian/Nearest Relative Consent



## EARLY RESULTS

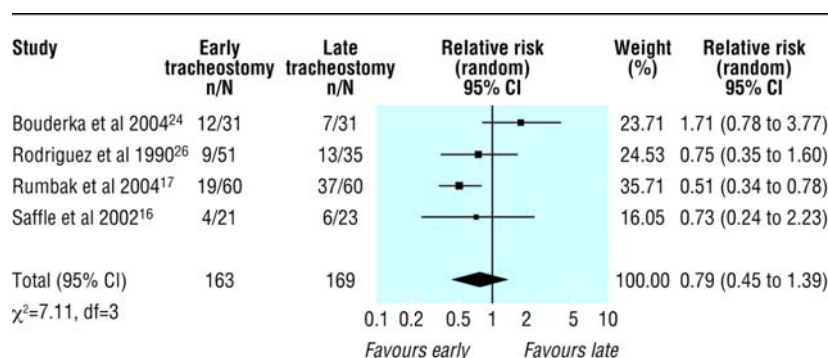
Though we can't do an interim analysis of the study, we can tell you that in the late group a significant number of patients were decannulated by day 10 and never required a tracheostomy. Thus there may possibly be an advantage to late tracheostomy. We're afraid we cannot give you any further information as we will not have the primary outcome (mortality) available until the end of the study.

## CURRENT EVIDENCE

Units vary in their practice of tracheostomy insertion across the UK, with some units preferring an early tracheostomy policy and others at the later end. The UK average time to insertion of a tracheostomy is ~day 10/11 of ICU admission.

There is still no clear evidence that the timing of tracheostomy effects mortality. Studies to date have been small in number, the largest being 120 patients, and all combined only results in 387 patients, and often in distinct patient groups such as burns, head trauma, medical and surgical groups.

A Forest plot of mortality of these trials does not show a clear effect of tracheostomy timing



Griffiths J, Barber VS, Morgan L, Young JD. Systematic Review and meta-analysis of studies of the timing of tracheostomy in adult patients undergoing artificial ventilation. *BMJ* 2005;330:1243-47.

Recent reviews have further shown that the Tracheostomy timing question remains an important unanswered question.

### USEFUL TRIAL CONTACT DETAILS:

**Trial Office (Vicki, Chris and Deirdre): 01865 857652 or 01865 857626**

**Linda Bower (Research Sister): 07766 991 550**

**Joanne Quinton (Multi-Sites Trial Co-ordinator): 07917 052 760**

**Trial Mobile (24 hours 7 days a week): 07900 580999**

**Randomisation Service: 01865 765615**

**Email: [TracMan@nda.ox.ac.uk](mailto:TracMan@nda.ox.ac.uk)**



Remember every patient counts in this first ICS nationwide trial.

# COLLABORATORS MEETING



TracMan is the largest tracheostomy timing trial in the world and it is aiming to recruit a total of 1,692 patients.

The Annual Collaborators Meeting will take place on  
Monday 3<sup>rd</sup> March 2008  
at 76 Portland Place in the Centre of London.

The meeting is free and travel expenses are paid for all delegates.

If you would like to reserve a place or get further information, please contact [TracMan@nda.ox.ac.uk](mailto:TracMan@nda.ox.ac.uk)