



**TracMan study
Review and progress report
Collaborators meeting Oct 2006**

Duncan Young
Oxford



Why are we doing the TracMan study?

- Because you said you want it
- Because it is long overdue
- Because the evidence to guide practice simply isn't there



Dear [personalised]

CLINICAL RESEARCH IN INTENSIVE CARE – WHAT MATTERS TO YOU?

The Intensive Care Society would like your opinion on clinical research priorities in intensive care. We are undertaking a research priority-setting exercise to identify areas where practising clinicians would like the Society to commission randomised controlled trials (RCTs).

etc.....
.....

Thank you for your time.



Duncan Young
Director of Research
The Intensive Care Society



Research Co-ordinator
The Intensive Care Society Trials Group



Dear [personalised]

The questions are in: what level of support will you give them?

A while ago we wrote to you asking which clinical research questions you thought should be tested within a randomised controlled trial. We had a huge response with over 750 suggestions put forward. After counting up the most frequently suggested questions we have identified 17 front runners, these are detailed on the enclosed questionnaire.

We would now like you to tell us how important you think each question is. All you have to do is assess how important you think it would be to try to answer each question within a clinical trial.



Duncan Young
Director of Research
The Intensive Care Society



Research Co-ordinator
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Does "early" tracheostomy (compared with "late" tracheostomy) alter outcome?



Because you said you want it

Because it is long overdue

Because the evidence to guide practice simply isn't there





- Tracheotomy first described 2000BC
- Modern tracheostomy technique attributed to Dr Chevalier Jackson 1909
- First percutaneous technique described 1957
- Ciaglia dilator technique described 1985

- Modern tracheostomy technique attributed to Dr Chevalier Jackson in 1909

TracMan results will appear on the 99th anniversary and be presented at international meeting on the 100th anniversary

- First percutaneous technique described in 1957

50th anniversary next year



Because you said you want it

Because it is long overdue

Because the evidence to guide practice simply isn't there

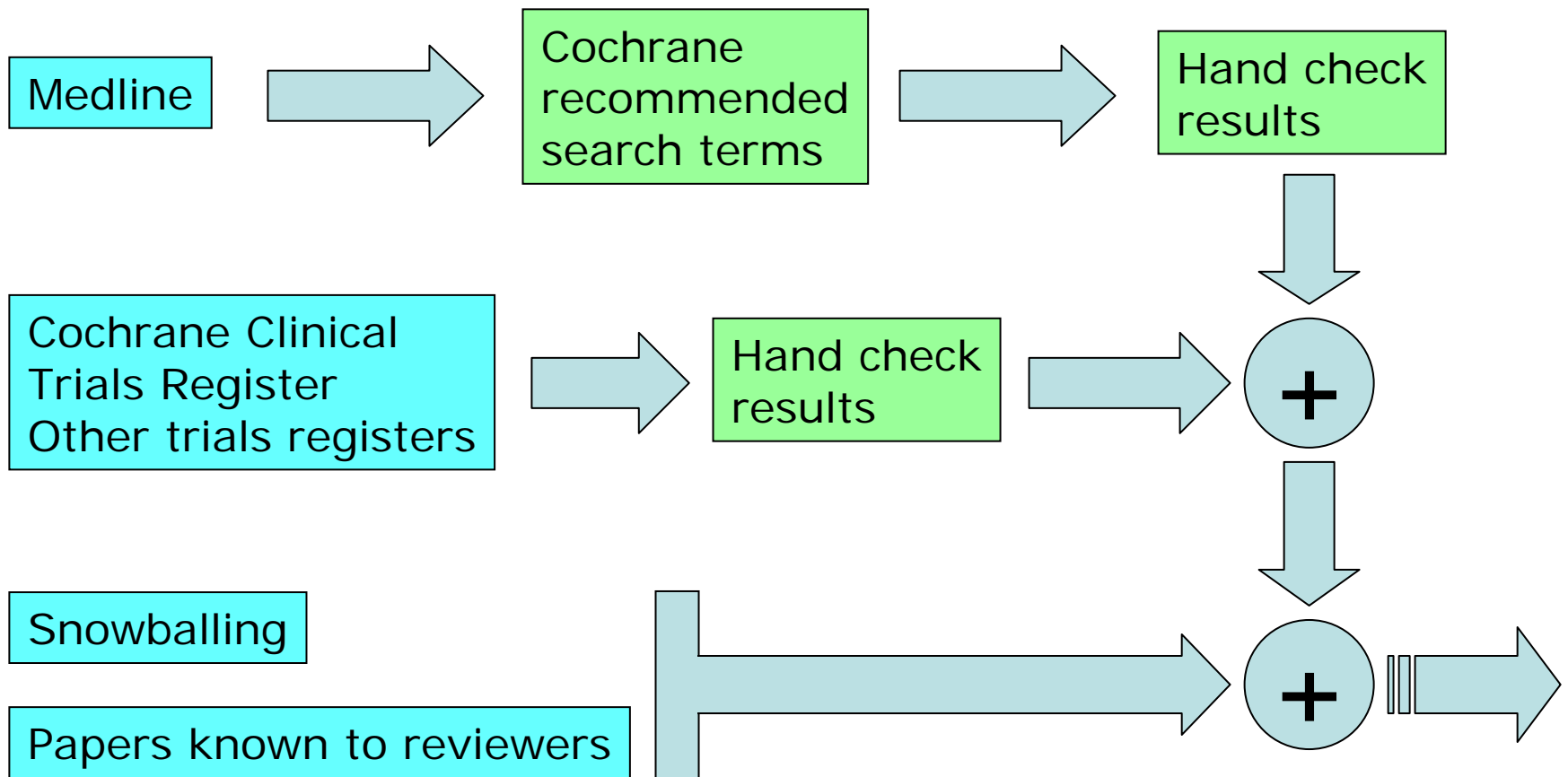


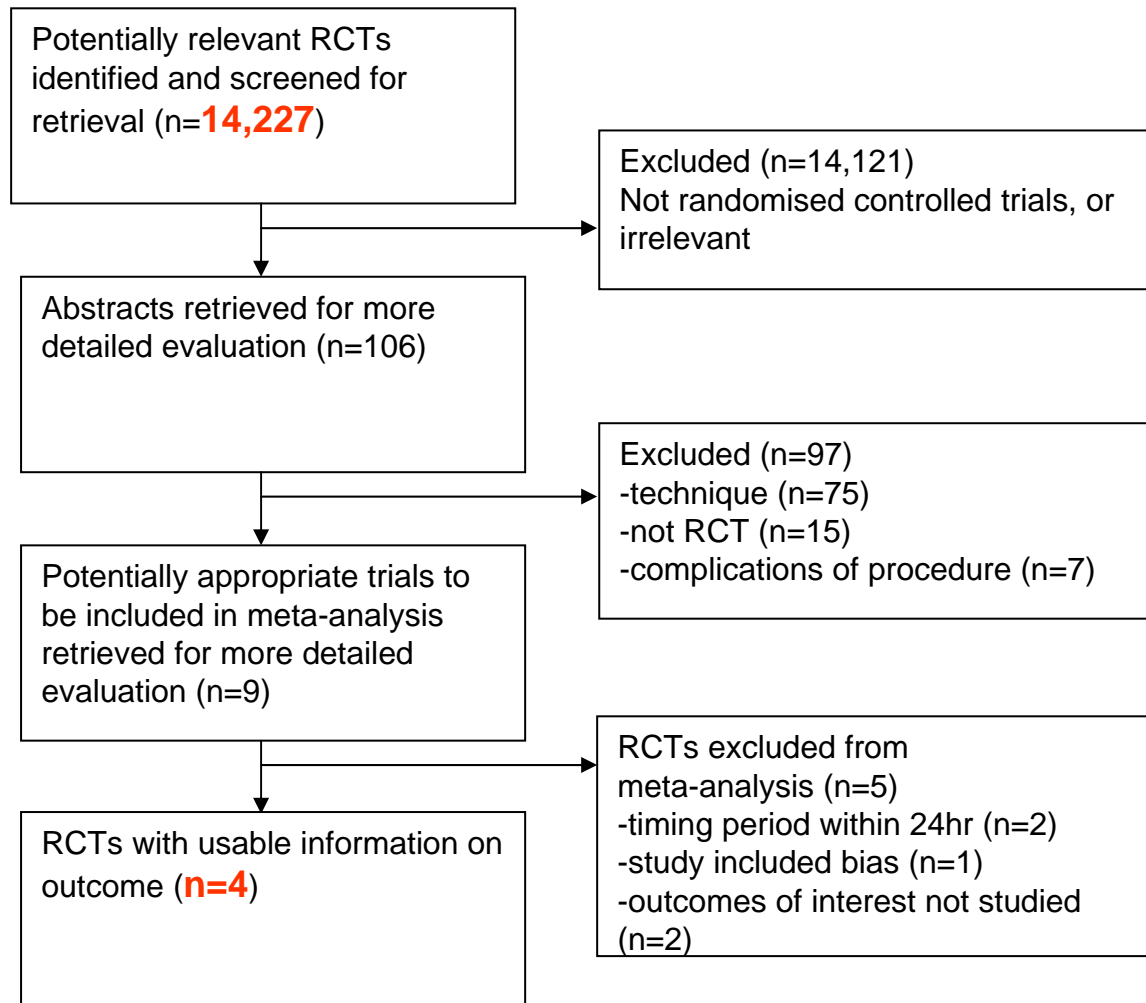
Systematic Review of Literature

Randomised controlled trials of either the *timing* of tracheostomy or the *use* of tracheostomy

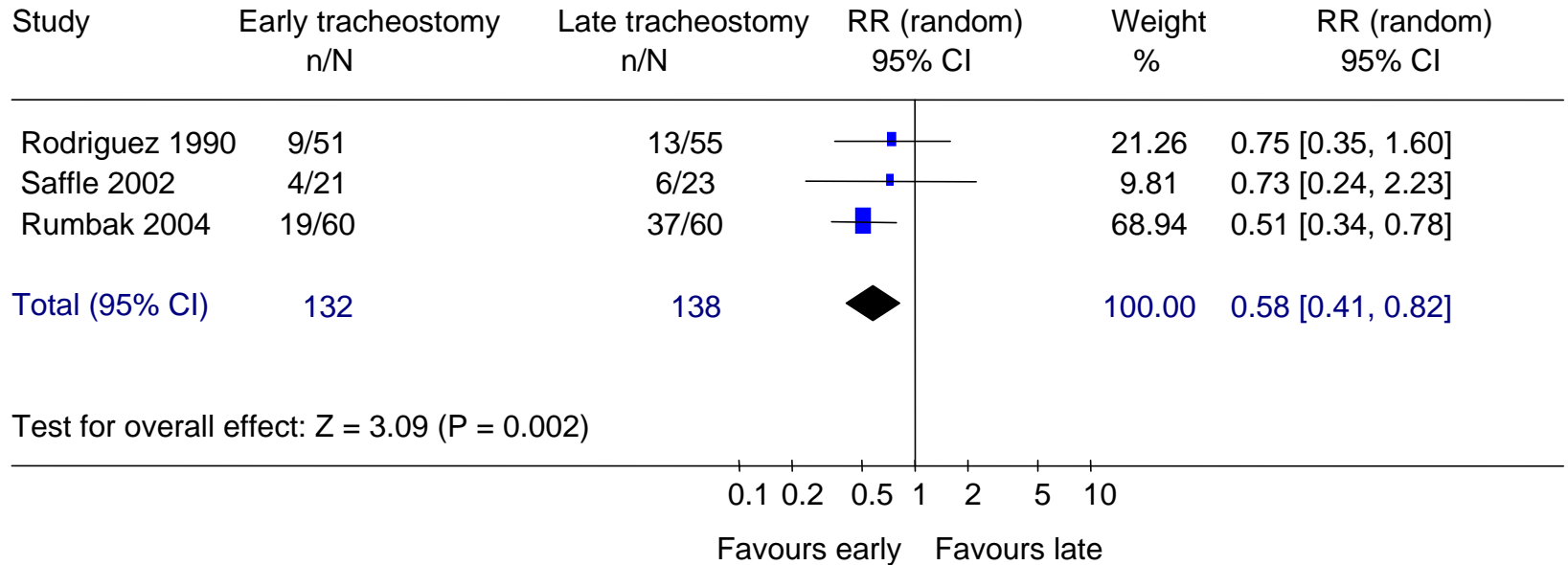
- Medline 1976 onwards
- Cochrane Library
- National Research Register
- NHS Trusts Clinical Trial Register
- MRC database
- NHS R&D HTA programme database
- British Heart Foundation Database

- + snowballing
- + phone a friend

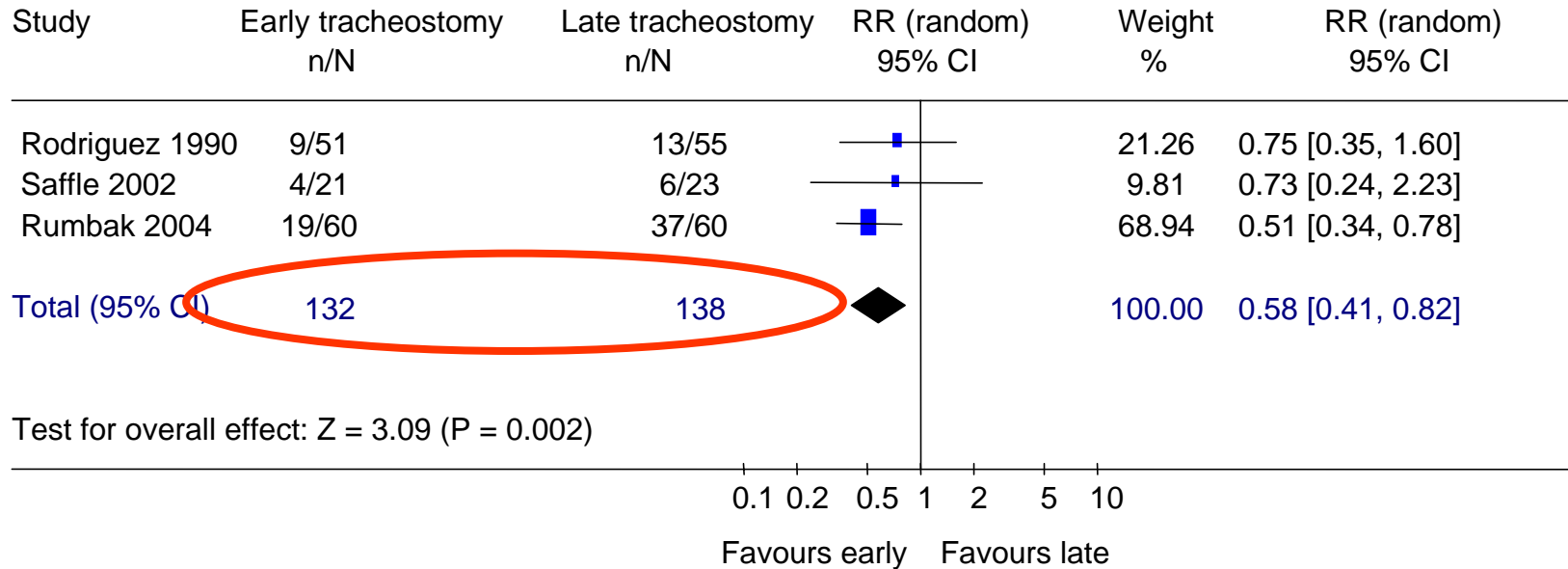




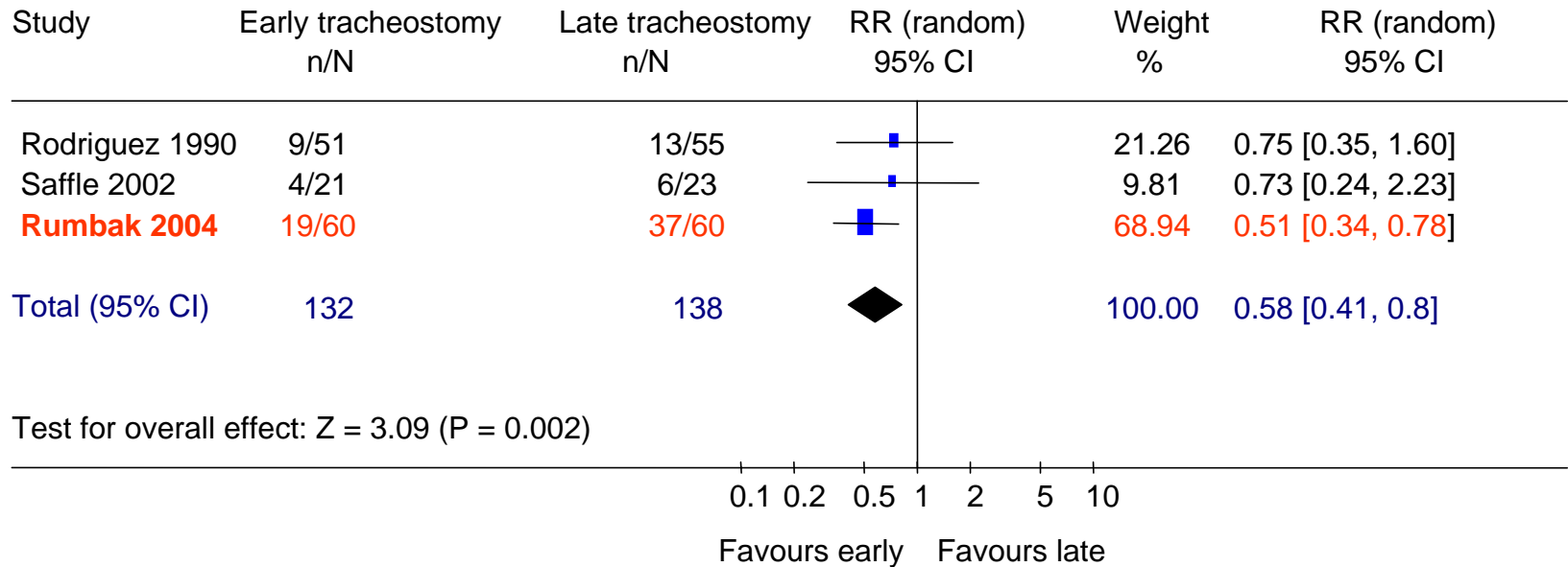
Meta-analysis of 3 RCTs of the effect of timing of tracheostomy on mortality



Meta-analysis of 3 RCTs of the effect of timing of tracheostomy on mortality



Meta-analysis of 3 RCTs of the effect of timing of tracheostomy on mortality



Early vs. late tracheostomy

Rumbak et al

Crit Care Med 2004 32: 1689-1694

Authors	Rumbak et al
Setting	3 Medical ICUs, USA
Patients	Medical, half were COPD
Randomisation	Good
Early Tracheostomy	days 1-2 of artificial ventilation
Late Tracheostomy	day 14 onwards
Nn	60/60
Hospital mortality, early tracheostomy	32%
Hospital mortality, late tracheostomy	62%



Early vs. late tracheostomy

Rumbak et al

Crit Care Med 2004 32: 1689-1694

Generalisable to UK ICUs?

Authors	Rumbak et al
Setting	3 Medical ICUs, USA
Patients	Medical, half were COPD
Randomisation	Good
Early Tracheostomy	days 1-2 of artificial ventilation
Late Tracheostomy	day 14 onwards
Nn	60/60

Hospital mortality, early tracheostomy 32%

Hospital mortality, late tracheostomy 62%

- *Other case series have average mortality of 38%*
- *Survey of 21 UK ICUs showed ICU mortality in tracheostomised patients of 21%*

Early vs. late tracheostomy

Rumbak et al

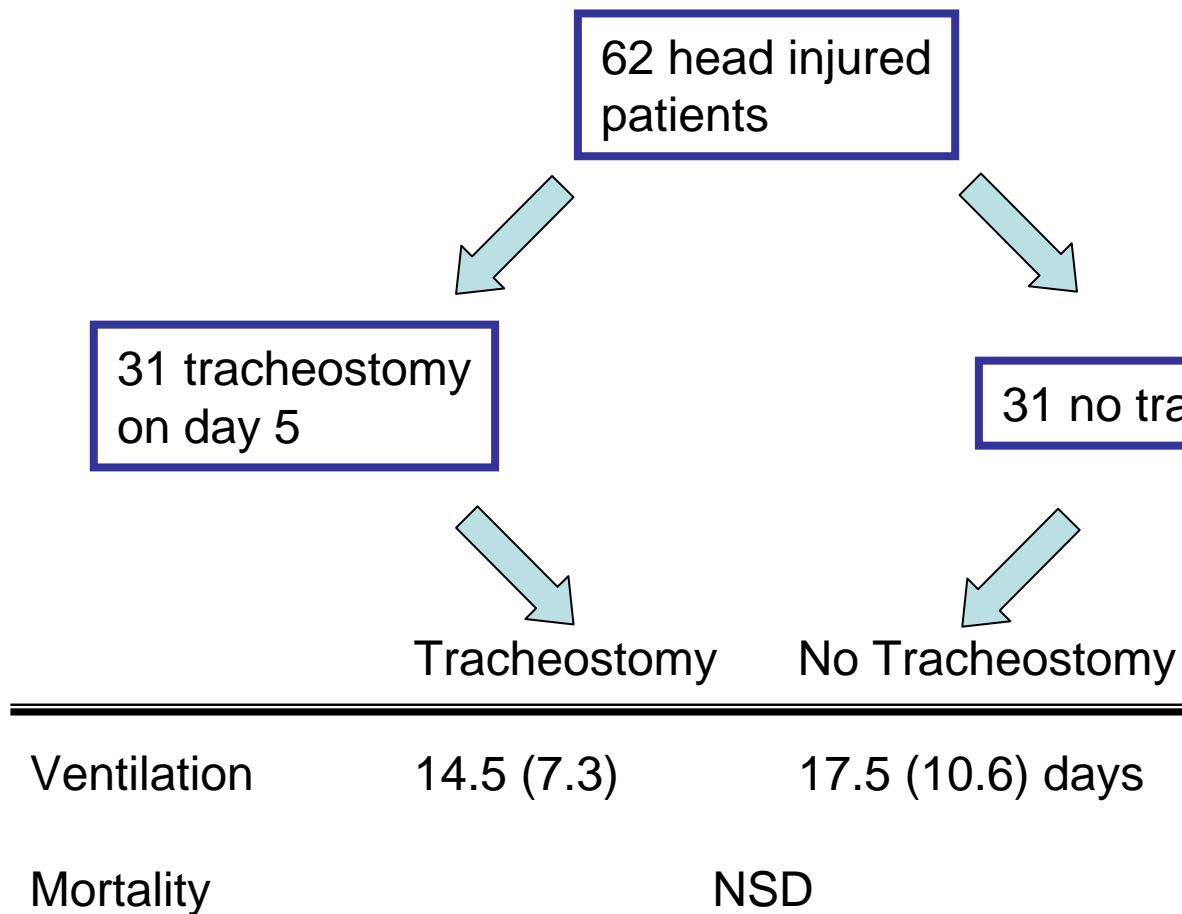
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**Good trial, but same results may not be achieved in the UK
UK Trial needed**



Bouderka et al
“Early tracheostomy versus prolonged endotracheal intubation
in severe head injury”
J Trauma 2004: 57;251-4



Barquist et al
“Early tracheostomy in trauma patients”
AAST abstract 2004

60 trauma victims

29 early tracheostomy
on day 8

31 late tracheostomy
after day 28

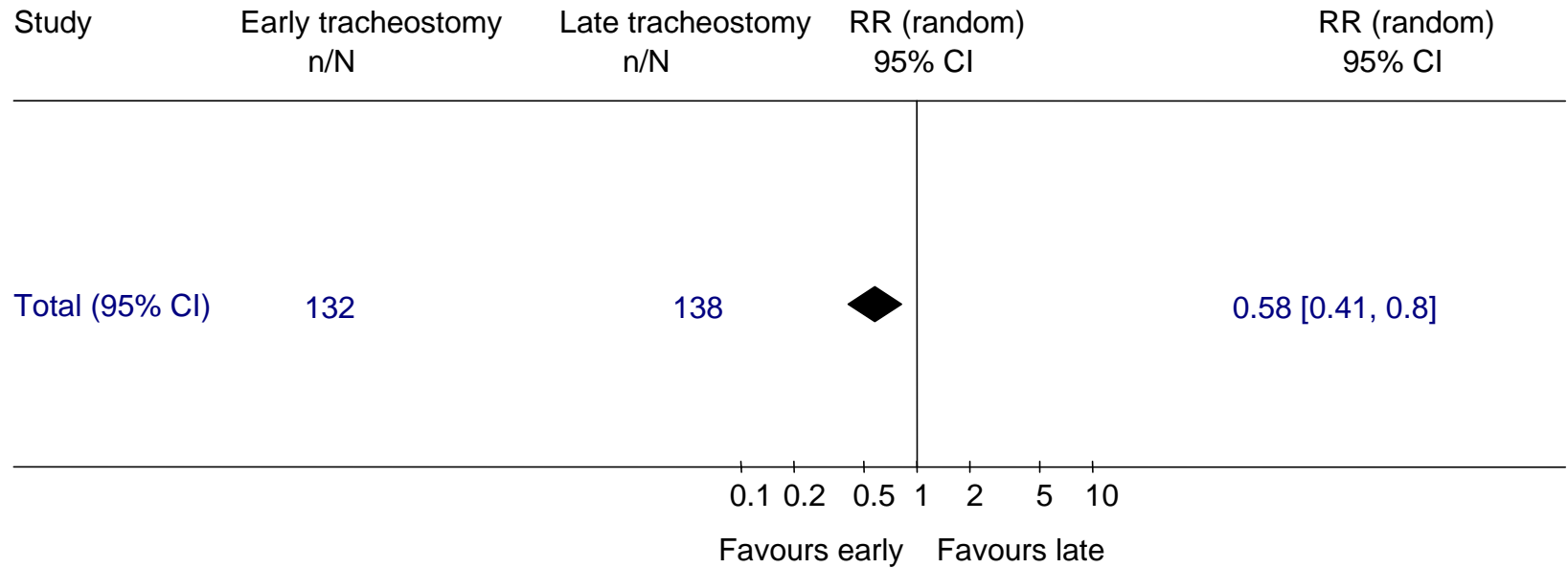
Early Tracheostomy

Late Tracheostomy

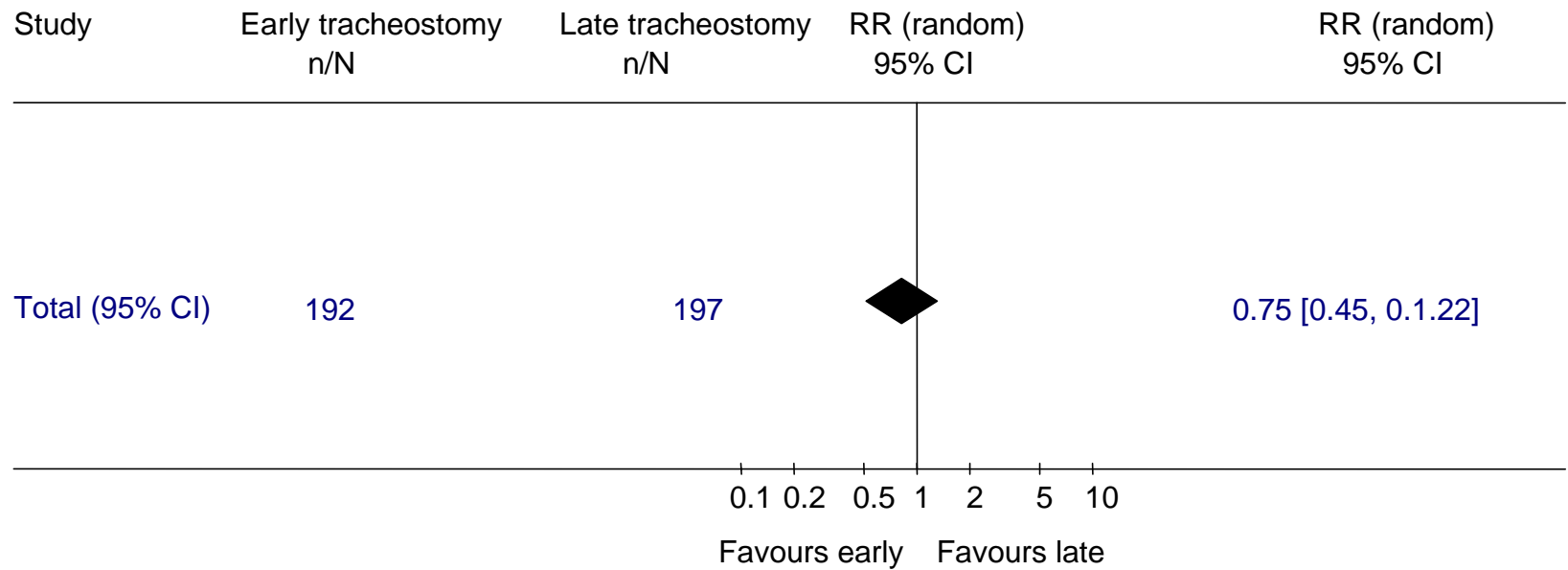
Ventilation free days	8.6 (7.9)	8.8 (9) days
Mortality	2/29 (7%)	5/31 (16%)



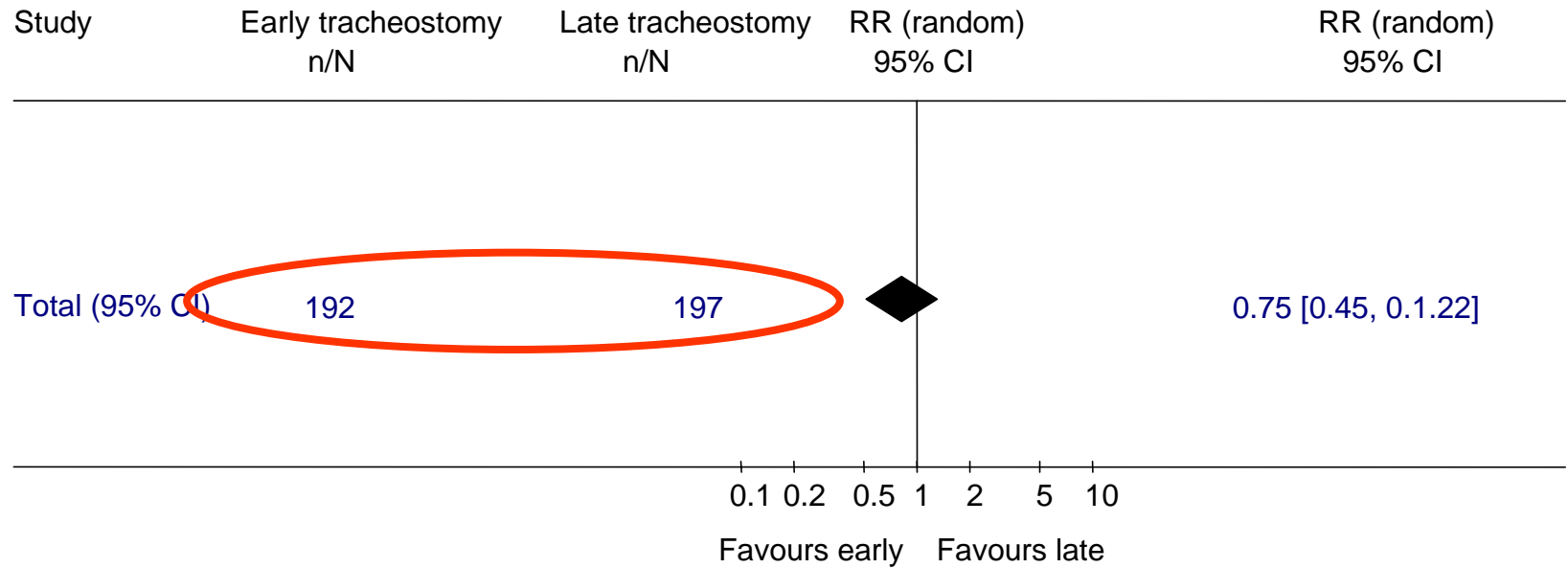
Meta-analysis of 3 RCTs of the effect of timing of tracheostomy on mortality



Meta-analysis of 5 RCTs of the effect of timing of tracheostomy on mortality



Meta-analysis of 5 RCTs of the effect of timing of tracheostomy on mortality





What is TracMan?

TracMan is a multicentre, unblinded, randomised controlled clinical trial of “early” versus “late” tracheostomy placement in critically ill adult patients.



“Early” tracheostomy:

Tracheostomy to be performed on day 1-4 post admission to ICU

Compared with

“Late” tracheostomy:

No tracheostomy before day 10 post admission to ICU



Which patients will be studied?

Patients who, within the first four days following ICU admission, the clinicians predict will require ventilatory support for a further 7 days or more.

Outcome measures

Primary outcome measure: Thirty day mortality

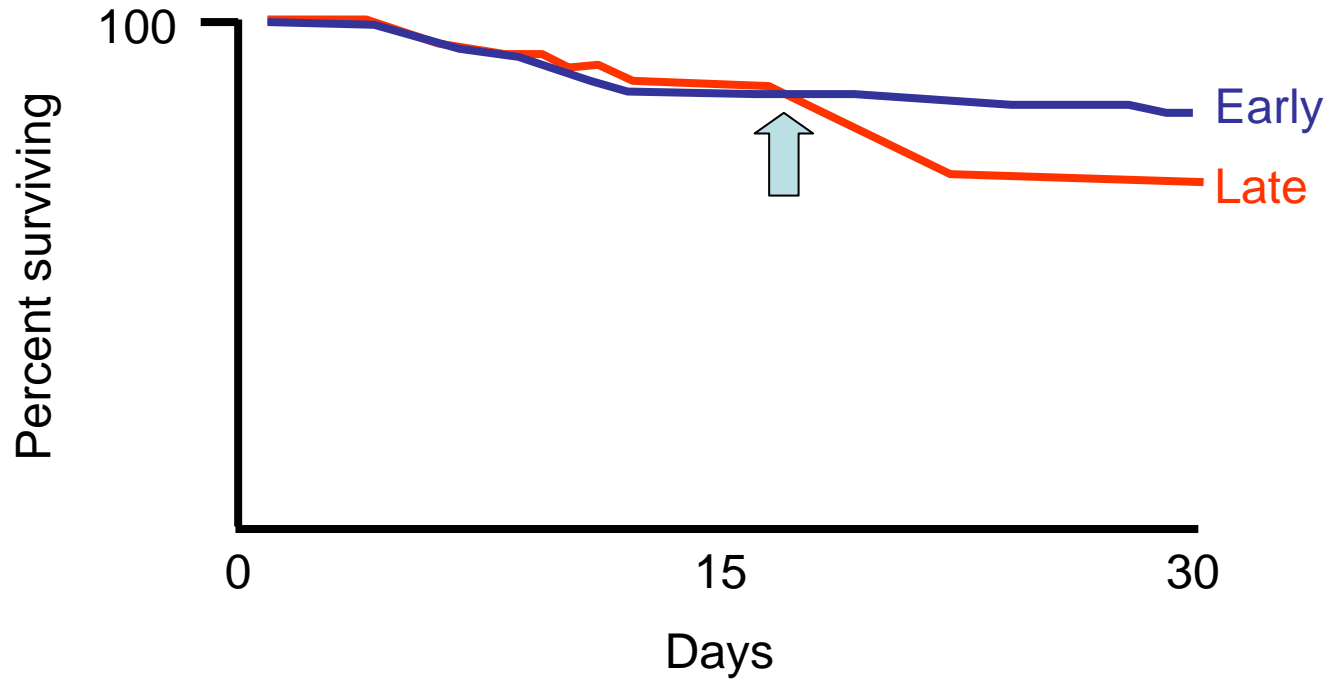
Secondary outcome measures: ICU length of stay
Hospital length of stay
ICU mortality
Hospital mortality
Number of days receiving sedatives
Antibiotic free days
(surrogate for pneumonia)

Outcome measures

Primary outcome measure: Thirty day mortality

Secondary outcome measures: ICU length of stay
Hospital length of stay
ICU mortality
Hospital mortality
Number of days receiving sedatives
Antibiotic free days
(surrogate for pneumonia)

Rumbak et al: Kaplan-Meier Curve



“Early” tracheostomy:

Tracheostomy to be performed on day 1-4 post admission to ICU

Compared with

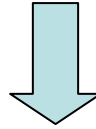
“Late” tracheostomy:

No tracheostomy before day 10 post admission to ICU

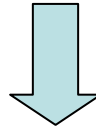
Ideally **“Late”** = usual practice



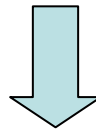
110 non RCT studies



14,962 patients

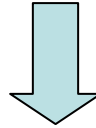


57 studies reported
tracheostomy timing

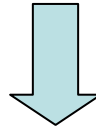


Unweighted mean = **10.8** days after admission

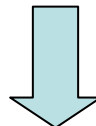
SICSAG 2002 annual report



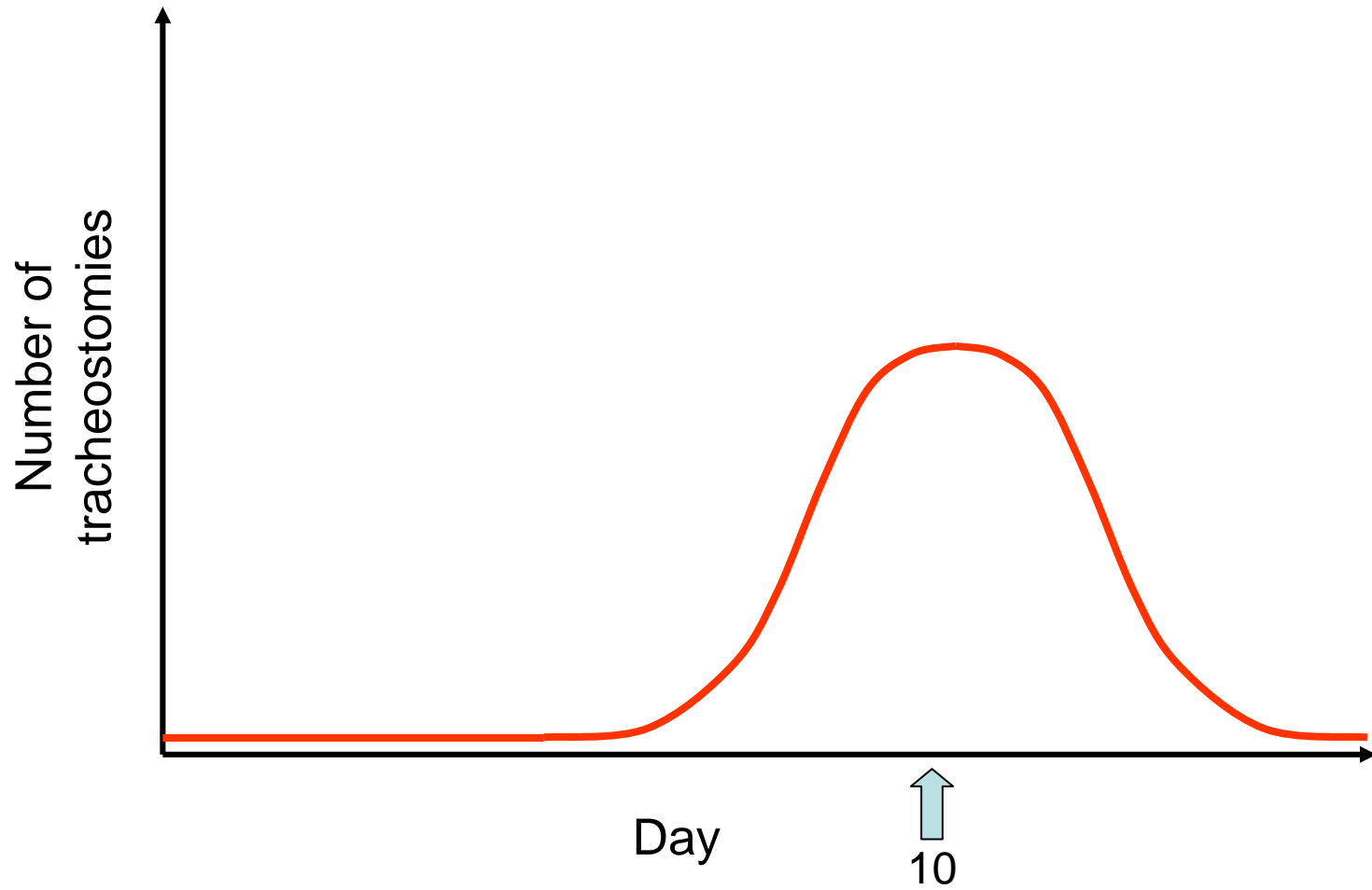
Data from 1999-2000 on tracheostomy use in Scotland

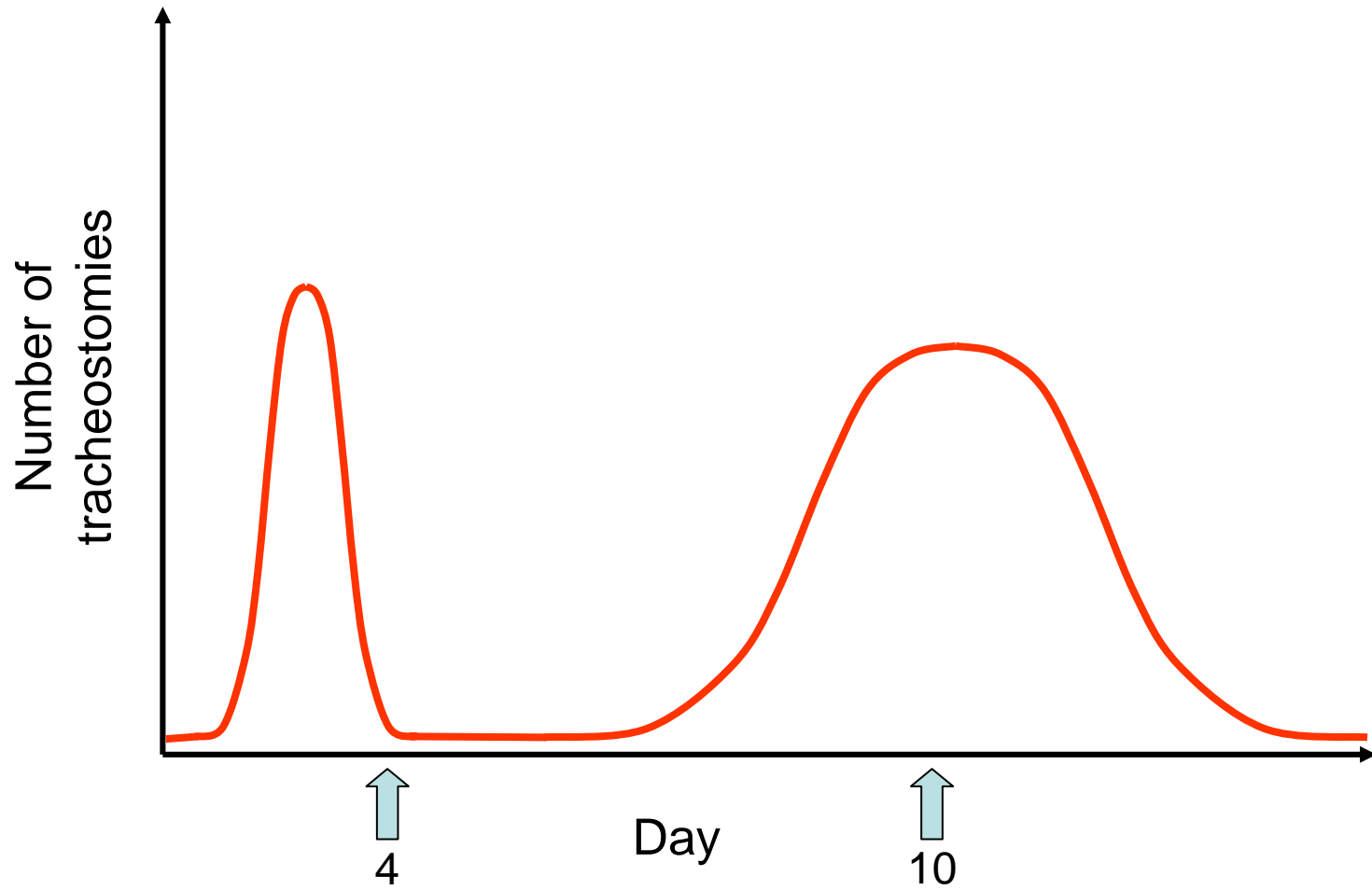


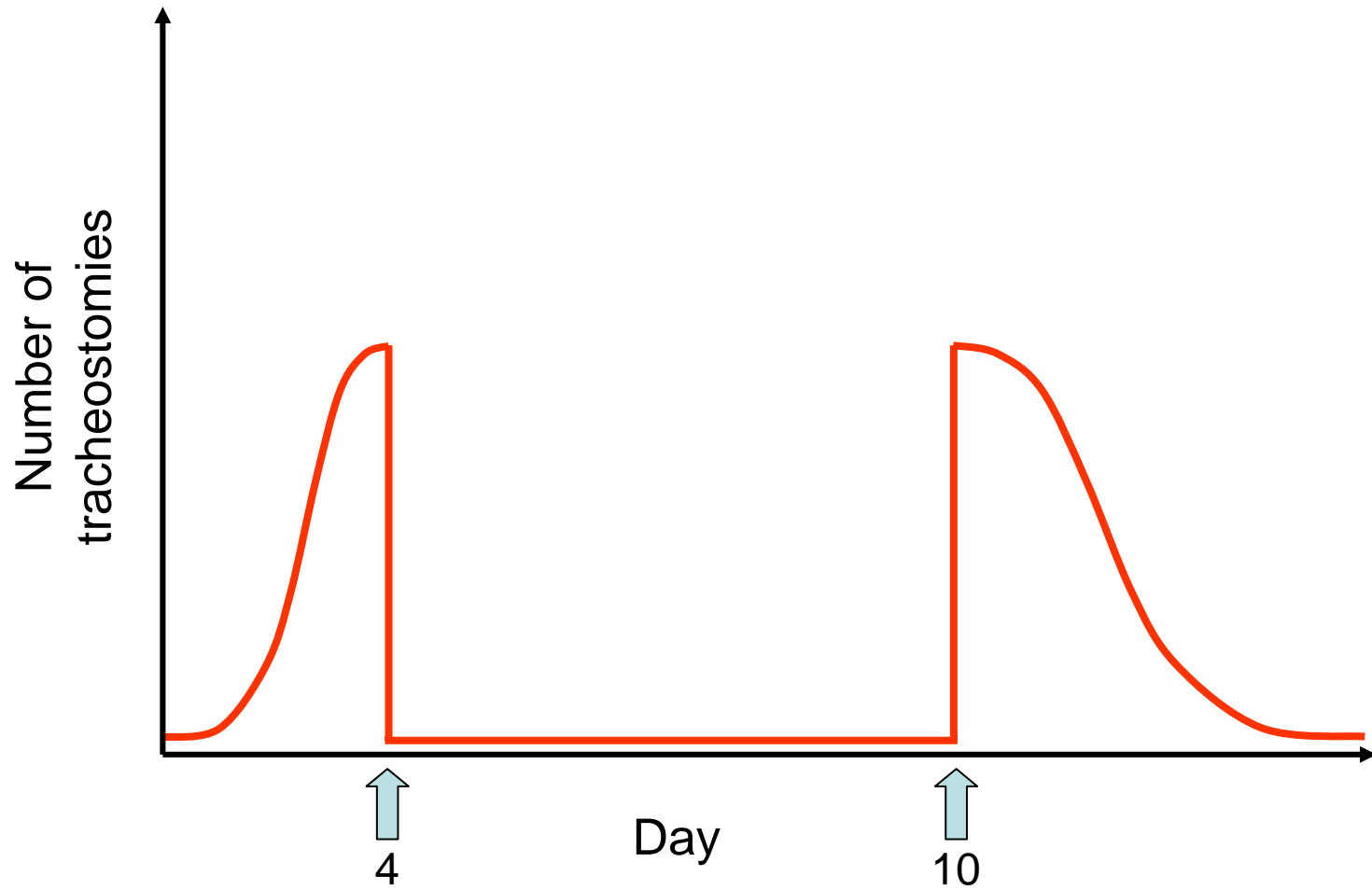
Median time for insertion was day 10-11 after admission



Range 6 and 16 days across individual Scottish units









TOP RECRUITING ICUs

<i>Centre code</i>	<i>Hospital</i>	<i>No. Pts recruited</i>
C002	Derriford Hospital - Plymouth	47
C014	Wythenshawe Hospital - Manchester	27
C022	St Thomas' Hospital - London	23
C004	Medway Maritime Hospital - Kent	18
C008	Yeovil District General Hospital	17
C010	Royal Devon & Exeter Hospital - Exeter	17
C021	Rochdale Infirmary	16
C031	Eastbourne District General Hospital	15
C006	Sunderland Royal Hospital	14
C007	James Cook University Hospital -Middlesbrough	14
C003	Royal Cornwall Hospital -Truro	13
C020	Bedford Hospital	12
C035	University Hospital Lewisham - London	11

Continue/...



RECRUITING ICUs

Centre

<i>code</i>	<i>Hospital</i>	<i>No. Pts recruited</i>
C015	Whiston Hospital – Liverpool	10
C019	Queen Alexandre Hospital – Portsmouth	10
C030	Royal Infirmary of Edinburgh	10
C009	Taunton & Somerset Hospital	10
C018	Southampton General Hospital	9
C001	John Radcliffe Hospital – Oxford	8
C016	Royal Surrey County Hospital – Guildford	7
C037	Manchester Royal Infirmary (Cardiac)	5
C048	University College Hospital – London	5

Continue/...



RECRUITING ICUs

Centre

<i>code</i>	<i>Hospital</i>	<i>No. Pts recruited</i>
C023	Worthing Hospital	4
C025	Kings College (Liver ICU)	4
C029	Dumfries and Galloway	4
C042	Peterborough District	4
C043	Weston General	4
C050	Castle Hill Hospital – Hull	4
C051	James Paget Hospital – Norfolk	4
C005	Southend Hospital	4

Continue/...



RECRUITING ICUs

<i>Centre code</i>	<i>Hospital</i>	<i>No. Pts recruited</i>
C013	Leeds General Infirmary	3
C017	York Hospital	3
C024	Royal Hampshire Hospital – Winchester	3
C027	Kingston Hospital – Surrey	3
C033	Ninewell Hospital and Medical School – Dundee	3
C039	Chorley Hospital – Lancashire	3
C054	Luton & Dunstable Hospital	3

Continue/...



RECRUITING ICUs

Centre

<i>code</i>	<i>Hospital</i>	<i>No. Pts recruited</i>
C011	Torbay Hospital	2
C028	Royal Alexandra Hospital – Paisley	2
C041	Barnsley District Hospital	2
C045	Leicester Royal Infirmary	2
C057	South Tyneside District Hospital	2
C061	Whittington Hospital – London	2
C026	Alexandra Hospital – Redditch	1
C036	Barnet Hospital – London	1
C038	Manchester Royal Infirmary (General ICU)	1
C040	Glan Clwyd District Hospital	1
C060	City General Hospital – Stoke on Trent	1



Total Number Patients Recruited End Sept 2006

395

Total number patients recruited to
all other tracheostomy timing trials
put together

387

TOP RECRUITING CONSULTANTS

Consultant	Hospital	Total pts
Duncan Wyncoll	St Thomas	17
Mark Carpenter	Sunderland Royal	12
Peter Macnaughton	Derriford	11
Ian Andrews	Eastbourne District	11
Chris Day	Royal Devon & Exeter	9
Jane Hurst	Bedford District	9
Elfyn Thomas	Derriford	8
Judith Wright	James Cook	8
Jon Howes	Yeovil District	8
Colin Ferguson	Derriford	7
Jo Rogers	Wythenshawe	7
Marthin Mostert	University Hospital Lewisham	7





TOP RECRUITING CONSULTANTS



<i>Consultant</i>	<i>Hospital</i>	<i>Total pts</i>	<i>First pt</i>	<i>Last pt</i>	<i>months active</i>	<i>monthly rate</i>
Duncan Wyncoll	St Thomas	17	Aug-05	Sep-06	18	0.94
Mark Carpenter	Sunderland Royal	12	Jun-05	Aug-06	15	0.8
Ian Andrews	Eastbourne District	11	Jun-05	Sep-06	15	0.73
Jon Howes	Yeovil District	8	Jun-05	Aug-06	11	0.72
Peter Macnaughton	Derriford	11	Jan-05	May-06	17	0.65
Chris Day	Royal Devon & Exeter	9	Aug-05	Sep-06	14	0.64
Jo Rogers	Wythenshawe	7	Jul-05	May-06	11	0.63
Marthin Mostert	University Hospital Lewisham	7	Jul-05	Jun-06	12	0.58
Judith Wright	James Cook	8	Jun-05	Mar-06	15	0.53
Jane Hurst	Bedford District	9	Mar-05	Aug-06	18	0.5
Colin Ferguson	Derriford	7	Jan-05	May-06	17	0.41
Elfyn Thomas	Derriford	8	Jan-05	Jun-06	18	0.4

TOP RECRUITING CONSULTANTS

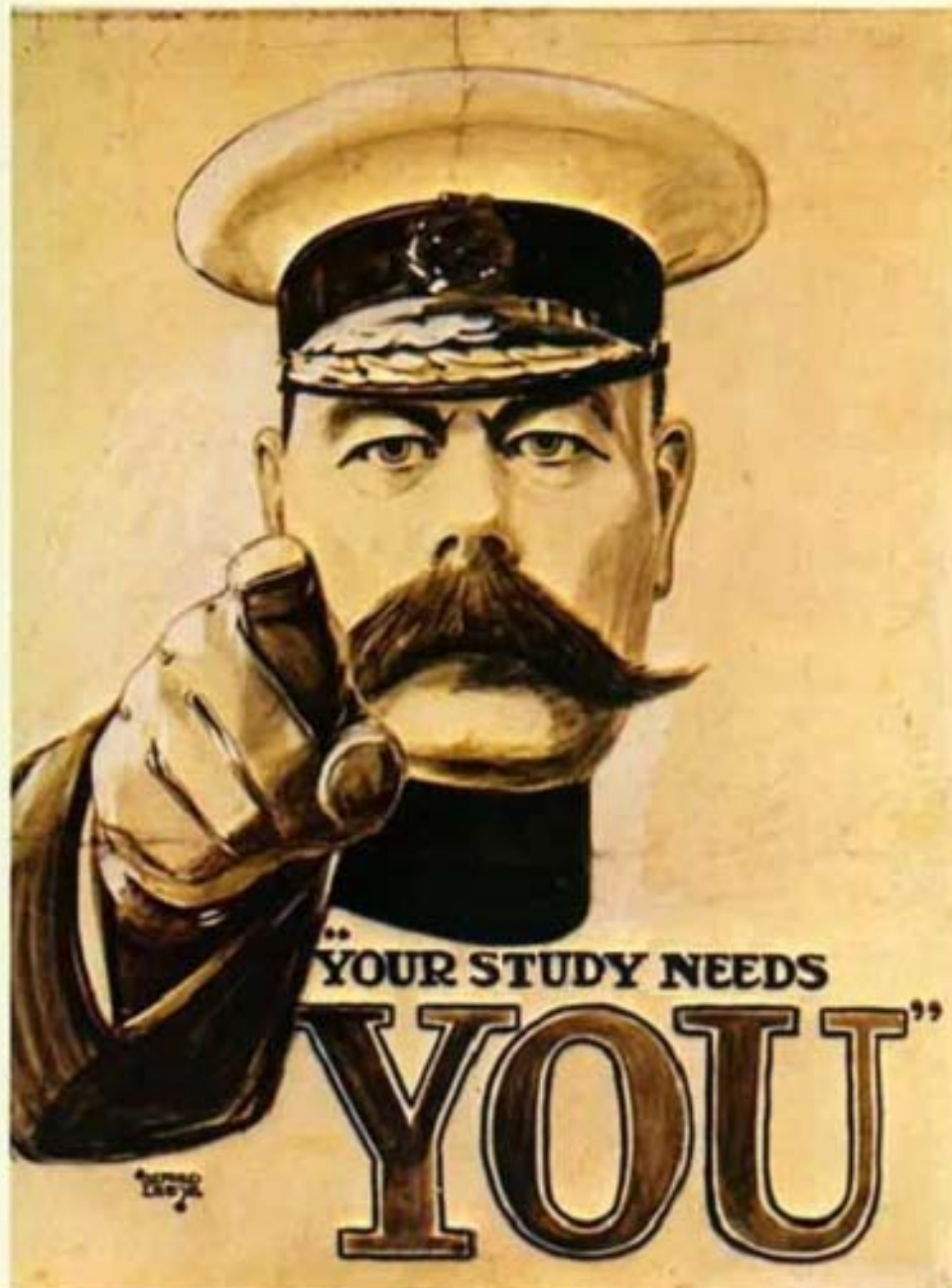
Name	Hospital	No. patients recruited since 1st April 06
James Down	University College London	5
Colin Ferguson	Derriford	4
Duncan Wyncoll	St Thomas	4
Elfyn Thomas	Derriford	3
Martyn Walker	Derriford	3
Andy Daykin	Taunton	3
Jane Hurst	Bedford	3
David Treacher	St Thomas	3
Ian Andrews	Eastbourne	3
Steve Cole	Ninewells	3
Mark Patten	Luton & Dunstable	3



We need a minimum of one patient a month from each ICU, just one!



UK Intensive Care
research needs
your help!





Trial Office email:
TracMan@nda.ox.ac.uk

Website:
<http://www.tracman.org.uk/>

Trial Office telephone:
01865 857652

