Hospitals with LREC approval

Barnet and Chase Farm Hospitals NHS Trust **Bedford Hospital Blackpool Victoria NHS Trust Bristol Royal Infirmary** Castle Hill Hospital, Cottingham * Cheltenham General Hospital Chesterfield & North Derbyshire Royal Hospital Chorley & District General Hospital City Hospital, Birminaham Crosshouse Hospital, Kilmarnock Diana Princess of Wales Hospital, Grimsby Friarage Hospital, Northallerton Glan Clwyd District General Hospital Glenfield Cardiothoracic Unit, Leicester Glenfield ICU, Leicester Glenfield Transport Team * Gloucestershire Royal Hospital * Hartlepool General Hospital Hull Royal Infirmary **Ipswich Hospital** Kettering General Hospital Leicester General Hospital Leicester Royal Infirmary Leighton Hospital, Crewe Luton & Dunstable Hospital * Macclesfield District General Hospital Manchester Royal Infirmary * Milton Keynes General Hospital Ninewells Hospital and Medical School * North Devon District Hospital, Barnstaple North Manchester General Hospital *

North Staffordshire NHS Trust Nottingham City Hospital *

Pilgrim Hospital, Boston *

Prince Philip Hospital, Llanelli

Princess Elizabeth Hospital, Guernsey Queen Elizabeth Hospital, Gateshead *

Queen Elizabeth Hospital, King's Lynn Rotherham District General Hospital *

Royal Bolton Hospital

Royal Hallamshire Hospital, Sheffield * Royal Liverpool University Hospitals *

Royal London Hospital **Royal Preston Hospital**

Royal Shrewsbury Hospitals NHS Trust

Salisbury District Hospital

Sandwell General Hospital Scunthorpe General Hospital *

Southend Hospital *

Southern Derbyshire NHS Trust

Southern General Hospital, Glasgow Southmead Hospital, Bristol

Southport & Ormskirk Hospital NHS Trust

South Tees Acute NHS Trust

University Hospital Aintree, Liverpool

University Hospital of Wales, Cardiff Walsgrave Hospital, Coventry

Warrington Hospital

West Suffolk Hospital, Bury St Edmunds Whipps Cross Hospital, London

Worcester Royal Infirmary **Wrexham Maelor Hospital**

indicates a hospital that has recruited to the trial

33 patients have been recruited to the trial by the end of June 2002.

CESAR Recruitment July 2001 - June 2002

Recruitment to CESAR

Tel. 020 7927 2376/2075 Fax. 020 7637 2853 www.cesar-trial.ora

Newsletter



Medical Statistics Unit London School of Hygiene and Tropical Medicine Keppel Street, London WCIE 7HT

Conventional Ventilation or ECMO for Severe Adilt Respiratory Failure

No. 3, July 2002

CESAR Collaborators' Meeting to be held in London on

Wednesday 30th October 2002

Local collaborators and a nurse from each online centre will be invited to attend and a collaborator from centres planning to participate will also be invited.

The programme will include an update on recruitment and referral patterns as well as workshops on data collection. Full details of the venue and programme will be circulated shortly and will also be available on our website. Let us know if you have any ideas - it's your day! Reasonable travel expenses will be paid.

Please make a note in your diary now.

LREC approval gives you choice

We are encouraging all ICUs to seek Local Research Ethics Committee (LREC) approval so that the choice is yours about considering an eligible patient for trial entry. So far 62 centres have LREC approval and a further 48 applications are in progress.

Patient eligibility

If you think that you have a potentially eligible patient (see inclusion and exclusion criteria) please ring the Clinical Advisory Team at Glenfield Hospital on 0116 287 1471 sooner rather than later. Many patients have been ventilated for too long (i.e. more than 7 days) before contact is made and then it is too late to consider trial entry.

Contacting the CESAR team:

Monthly recruitment

Nikki Jones

30

25

20

15

10

radiopage: 0769 321 1582 email: nikki.jones@uhl-tr.nhs.uk **Ann Truesdale**

tel: 020 7927 2376 fax: 020 7637 2853 email: ann.truesdale@lshtm.ac.uk

The CESAR Trial is funded by NHS R&D HTA programme and costs of treatment are provided by the National Specialist Commissioning Advisory Group (NSCAG) www.cesar-trial.org

Cumulative total

Trial posters

Posters aimed at helping those involved in the recruitment process have been distributed to all

online centres. The posters highlight the patient inclusion and exclusion criteria and what to do if you think you have an eligible patient. Please display these in a prominent place on your unit to remind staff about the trial. Please also ensure that the name of the local collaborator and named nurse are written in the box at the bottom of the poster. If you require any further copies please contact the Data Co-ordinating Centre (DCC) in London.



Ann Truesdale with the CESAR stand at the ICS conference in Edinburgh,

Data Collection

Data collection forms

Thank you to all the nurses and doctors who continue to collect and return data for CESAR patients. We appreciate your help with this. It is essential that the original copy of each registration and assent form is kept at the recruiting hospital, **even if the patient is transferred**. Please also remember that if you are posting datasheets to us it is very important that the originals are kept with the patient's notes and photocopies are sent to us.

Data queries

Our database now runs ongoing data validation checks which will result in regular queries being made to centres by fax and phone. Some of you will already have received these and we'd like to thank you for responding so quickly to these. We would appreciate your help in resolving any future queries as quickly as possible.

And finally...

a special thank you to Janice Garner for co-ordinating the data collection and return at the ECMO Unit in Glenfield Hospital, Leicester.

Frequently Asked Questions

In each newsletter we hope to feature some of your frequently asked questions. These and other FAQs are available to download from the website.

Q: I am concerned about the risks of transferring patients to Leicester

A: A specialist team with expert knowledge and experience in managing these types of patients will carry out the transfer of patients in the trial. This team is based in Glenfield and we view the transfer of patients as part of the evaluation of ECMO. ECMO is clearly a specialist treatment currently only carried out by Glenfield Hospital during this trial. As such we must be able to transfer patients safely to Leicester in order that we can manage patients with ECMO.

The transport team will discuss the risks of transfer with the relatives and is responsible for gaining assent for transfer as separate from assent for the trial. If the transport team or the relatives are not happy for the patient to be transferred, then the patient will remain where he/she is. The analysis will be by intention to treat i.e. the outcome will be recorded in the arm of the trial to which the patient has been allocated.

If you have a clinical query about ECMO or the CESAR Trial please contact Nikki Jones.

CESAR Trial profile - the 6 month follow-up

It is very important not just to look at the short-term, but also to compare the longer-term health of people who had conventional ventilatory treatment with those who had ECMO.

Survivors at 6 months post randomisation are interviewed and examined by a researcher, preferably at home. In cases where this is not possible a telephone interview is attempted. If relevant, a carer will be asked to complete a Caregiver Strain Index questionnaire to assess the effect of long-term illness on carers.

The assessment includes general measures of health status (SF-36, EQ-5D), assessment of respiratory related quality of life (St George's Hospital Respiratory Questionnaire), cognitive function (Mini Mental State Examination (MMSE)) and psychological state (Hospital Anxiety and Depression scale). There is also a patient costs questionnaire, with responses prompted by an events diary given at discharge. Lung function is assessed by spirometry.



I-r: Andy Wilson, Jo Sanderson-Mann, Paul Sinfield and Hillary Watkinson

Andrew Wilson is Reader in General Practice at the Department of GP and PHC at the University of Leicester and coordinates the 6 month follow-up programme. The researchers, Jo

Sanderson-Mann and Paul Sinfield, are conducting these assessments in addition to their other duties in the department. They have been trained in spirometry by the Pulmonary Function Laboratory staff at Glenfield Hospital and in using the MMSE by the Academic Department of Psychiatry at the University of Leicester. Secretarial support is provided by Hillary Watkinson. The assessment takes approximately one hour to complete, but travel time is considerable. The furthest distance travelled so far has been a day trip to Dundee!!

Steven Robertson is the CESAR Trial Data Management Co-ordinator at the London School of Hygiene & Tropical Medicine. He works closely



with Andrew Wilson organising the follow-up visits and is responsible for the data when they are returned to the DCC in London. He is also involved in the development of questionnaires and data collection forms used for the follow-up and also for the trial in general.

Forthcoming events

ICS Trainee Division Annual Meeting, Belfast 15-16 August 2002
For details visit the trainee section of the ICS website http://www.ics.ac.uk/ICS.html

BACCN Conference 2002, University of Warwick, Coventry, 10-12 September 2002 For further details please contact Conference Secretariat on 01794 511331/2 or visit www.baccn.org.uk/

European Society of Intensive Care Medicine 15th Annual Congress, Barcelona, 29 September - 2 October 2002

For further details please see www.esicm.org/frame.html