



The Research Nurse Experience at Wirral Hospitals

Tony Lake
Rheumatology Research Nurse



PERSONAL BACKGROUND

- RGN 1990
- BSc (Hons) 2000
- ORTHOPAEDIC SPECIALIST NURSE 2000
- CLINICAL TRIAL COORDINATOR 2003



Background

- Trials office set up by Dr George in 1996, employed 1 part time research nurse performing 3-4 trials a year
- Now 1 full time coordinator with up to 13 trials being performed during the year



THE TEAM

- 2 RHEUMATOLOGY CONSULTANTS
- 1 SpR
- 1 RESEARCH NURSE/TRIAL CORDINATOR
- 2 RHEUMATOLOGY NURSES
- 1 ANP/INFUSION NURSE



PRINCIPAL INVESTIGATOR

- Dr. E. GEORGE CONSULTANT RHEUMATOLOGIST
- SET UP DEPARTMENT 12 YEARS AGO
- INTERESTS RA Os
- RESPONSIBLE FOR ALL CLINICAL TRIALS CONDUCTED IN RHEUMATOLOGY



SUB INVESTIGATOR

- DR CHIU CONSULTANT RHEUMATOLOGIST
- PREVIOUS EXPERIENCE IN RESEARCH
- INTERESTS CHRONIC PAIN AND
- FIBROMYALGIA
- ROLE BACK-UP FOR PI
- RESPONSIBLE FOR CONSENT, PHYSICAL EXAMINATION, REVIEW AE's, SAE's, BLOODS, X-RAYS, etc



SpR

- ALSO HAS ROLE AS SUB-INVESTIGATOR WITH SAME RESPONSIBILITIES FOR CONSENT EXAMINATION AND FITNESS OF PATIENT TO ENTER CLINICAL TRIAL



RHEUMATOLOGY NURSES

- ASSIST WHEN COORDINATOR ON HOLIDAY
- WILL PERFORM VENEPUNCTURE , ECG, DATA COLLECTION
- ACT AS INDEPENDENT JOINT ASSESSORS
- ASSESS AE's, SAE's
- TRAINED TO ICH/GCP STANDARDS



ANP/INFUSION NURSE

- ARRANGES DAY CASE ADMISSION FOR INFUSION
- SETS UP INFUSION
- MONITORS PATIENT WHILST ON INFUSION




THE JOURNEY

- APPROACHED BY SPONSOR
- DISCUSS WITH DR GEORGE
- FEASIBILITY STUDY
- SITE VISIT
- MREC/LREC APPLICATIONS
- R&D APPROVAL
- INVESTIGATOR MEETING
- SITE INITIATION
- RECRUITMENT



ROLE OF CLINICAL TRIALS NURSE

- Ensure Ethical approval of the trial, liase with the ethics committee and adhere to regulatory requirements
- Adhering to the Protocol, data collection
- Recruitment of patients
- Ensuring safety of the patient
- Ensuring the patient is fully informed of all procedures and potential risks
- Advocate for the patient
- Report adverse events
- Invoices and tracks payments
- Study performed to GCP/ICH standards



Ensure Ethical approval of the trial, liaise with the ethics committee and adhere to regulatory requirements

- MREC
- LREC
- Research and Development approval
- Written agreement between parties



Adhering to the Protocol, data collection

- AS WELL AS PI RESPONSIBLE FOR ENSURING THAT NO PROTOCOL DEVIATIONS OCCUR
- COLLECTION AND TRANSCRIBING OF BOTH WRITTEN AND ELECTRONIC DATA CAPTURED
- ALL DATA IS TRUE AND ACCURATE



Recruitment of patients

- Agree and set targets for recruitment with sponsor
- Ensure target is achievable
- Be aware that recruitment is competitive
- Use various tools for recruitment e.g. databases, media advertising

Ensuring the safety of the patient

BBC NEWS | Health | Drugs volunteer's 'living hell' - Microsoft Internet Explorer

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Drugs volunteer's 'living hell'

One of the men given a dummy pill as part of the clinical trial that left six men seriously ill has said the study was like "Russian roulette".



VIDEO Raste Khan

Raste Khan said that the test ward in north-west London became a "living hell" as the men spasmed in agony.

Two remain critically ill but four have shown signs of improvement.

A solicitor representing one man said it was not clear if successful animal tests had been previously held.

BBC LONDON
Travel, features and more from the BBC website for London

DRUGS TRIAL

LATEST STORIES

Northwick Park & Marks Hospitals
Drugs volunteer's 'living hell'

- ▶ Scientist defends clinical trials
- ▶ Trial student 'worried for friend'
- ▶ Six taken ill after drug trials

BACKGROUND

- ▶ Human drug trials 'fundamental'
- ▶ Making a success out of drug tests

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Internet



Advocate for patient

- Ensure patient is suitable
- It is in the best interest of patient
- Patient is not pressured
- Has sufficient time to consider trial

Report Adverse Events



"If you remember, I did mention possible side-effects."



Invoices and tracks payments

- Ensure payments offered reflect work undertaken
- Seek reimbursements for patient expenses
- Invoice sponsors for work undertaken
- Payments made in a timely manner



Study performed to GCP/ICH standards

- All clinical trials must conform to GCP/ICH
- The rights and safety of participating subjects are protected.
- The data resulting from the trial is complete accurate and unbiased.



TRIALS

- COMMERCIAL
- NON COMMERCIAL



NON COMMERCIAL TRIALS

- SPONSORED BY EDINGBURGH AND MANCHESTER UNIVERSITIES



COMMERCIAL TRIALS

CURRENTLY SPONSORED BY VARIOUS DRUG
COMPANIES



CLINICAL TRIALS 2008(14)

- CONDOR
- BIOGEN (2)
- MIRROR
- TRACE
- PRISM
- AMGEN
- CDP-015
- ASPECTS
- ASCEND
- EXTRA
- CAPRA
- ABBOTT M10-261
- ROCHE
- BLISS




NON RECRUITING CLINICAL TRIALS 2008

- BIOGEN
- MIRROR
- PRISM
- AMGEN
- CDP-015
- ASPECTS
- ASCEND
- BLISS



CURRENT RECRUITING CLINICAL TRIALS

- CONDOR
- TRACE
- ABBOTT-M10 261
- CAPRA



PROPOSED CLINICAL TRIALS 2008/2009

- ABATACEPT
- ROCHE
- QUINTILLES
- FIBROMYALGIA

Consent





CONSENT

- WRITTEN CONSENT
HAS TO BE OBTAINED
PRIOR TO ANY STUDY
RELATED PROCEDURE



Informed consent

- Informed consent must comply with ICH GCP and the declaration of Helsinki
- Written informed consent forms must be approved by the EC prior to their implementation
- If any new safety information comes to light it must be communicated to the patient and the consent form must be updated



Informed consent cont....

- No influence or coercion must be placed on the patient
- If the patient is unable to provide informed consent the patients legally acceptable representative must be informed
- The language used in the oral and written information should be understandable
- Prior to the subject's participation in the trial the written informed consent should be signed and dated personally by the patient
- The subject should receive a copy of this signed consent



CONSENT

- Patient is aware of right to refuse without any penalty.
- Appropriate environment.
- Face to face
- Open & honest.
- Ample time to reflect.
- Opportunity to ask questions.
- Process used as opportunity to empower & educate patient.



Conducting a Clinical Trial

- Protocol must be scientifically sound
- Recruitment
- Information and consent
- Case report form/ Data Collection
- Clinical examination/Joint examination
- Drug administration
- Samples
- Maintain patient confidentiality and safety



CURRENT ISSUES

- ARCHIVING
- STAFF ROTATION
- MONITORING
- RECRUITMENT



ARCHIVING

- HAS TO BE KEPT FOR 15 YEARS
- 2 YEARS AFTER LICENCE
- CURRENTLY STORED OFFICE , WARD 27 AND OFF SITE IN WARRINGTON
- ELECTRONIC DATA CAPTURE STILL GENERATES PAPER!



STAFF ROTATION

- SpR ROTATED ON REGULAR BASIS
- NEW STAFF NEED GCP/ICH TRAINING AND CERTIFICATION
- TRAINED IN THE PROTOCOL OF VARIOUS STUDIES



MONITORING

- TIME
- OFFICE SPACE
- NUMBER OF TRIALS
- SOURCE DOCUMENTS



RECRUITMENT

- MORE COMPETITION
- UK GENERALLY MORE EXPENSIVE
- 30% OF UK SITES FAIL TO RECRUIT
- UK TAKES LONGER TO APPROVE STUDY
(NOW IMPROVING)



Relevance of Clinical Trials in Rheumatology

- Development of new treatments
- Comparisons of treatments
- Providing research based evidence
- Support clinical practice
- Financing projects /salaries



BENEFITS TO PATIENT

- SEEN BY MEDICAL STAFF ON REGULAR BASIS
- EASIER CONTACT WITH DEPARTMENT
- DISEASE CONTROL
- CAN BE COMMENCED SOONER ON TREATMENT



BENEFITS TO DEPARTMENT

- FINANCED :-
- RESEARCH NURSE/SPECIALIST NURSE
- DAY CASE UNIT
- CONSULTANT NURSE
- OSTEOPORSIS NURSE
- METROLOGIST
- SUPPORT SECRETARY
- EQUIPMENT
- EDUCATION/CONFERENCES

ANY QUESTIONS

