

31044 – Clinical Trial Registration

The intervention part of this study was approved by the National Institute for Health Research (Birmingham and the Black Country Comprehensive Local Research Park – RM&G reference number 1268) and Warwickshire Primary Care Trust (reference WAR230909). This has been included in the Materials and Methods section of the manuscript (page 8).

Copies of the approval documents are included below.



Professor Sudarshan Ramachandran



Dr G I Hackett
Consultant in Urology (Sexual Medicine)
Good Hope Hospital
Holly Cottage Hospital
Fisherwick Road
Lichfield
WS14 9JL

Thursday, 25 June 2009

NHS
**National Institute for
Health Research**

Birmingham and the Black Country
Comprehensive Local Research Network
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Birmingham Research Park
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LETTER OF RESEARCH MANAGEMENT AND GOVERNANCE (RM&G) PERMISSION

Research Management and Governance Permission has been granted by the Consortium RM&G Office on behalf of the Birmingham and the Black Country RM&G Consortium Trusts. The Chief Investigator named in this letter has permission to undertake the following research activity in the NHS Trust(s) identified below.

Chief Investigator Name: Dr G I Hackett

Date of Issue: 25/06/09

Project Title:	Clinical and biochemical improvement in type 2 diabetic parameters in type 2 diabetic men with symptomatic testosterone deficiency syndrome (TDS). A double blind, placebo controlled study of depot testosterone undecanoate (NEBIDO) versus placebo	
Consortium RM&G Ref ID:	1268	
Start/End Dates:	Start Date: 25/06/09	End date: 31/12/2010
Chief Investigator:	Dr G I Hackett	
Chief Investigator Employer:	Self Employed	
Funding & Funding amount:	Bayer plc £325,000	
Sponsor:	Dr G I Hackett	

Trust Registered:	Principal Investigator	Research Site
Birmingham East and North Primary Care Trust (BENPCT)	Dr Robert Flacks	Manor Practice
	Dr Peter Ingham	Tudor Medical Practice

Trust Service/Directorate: Primary Care / GP Practices

Thank you for informing the BBC CLRN RM&G Consortium of the above research.

Confirmation of RM&G Permission

On behalf of the BBC CLRN RM&G Consortium, I am please to confirm RM&G Permission has been granted for the Consortium Trust(s) and Research Site(s) as stated above.

Conditions of RM&G Permission

This permission is given provided that you comply with the conditions as set out in the attached. You are advised to study the conditions carefully.

If you require any further assistance, please call the Consortium RM&G Office stating your **RM&G Reference Number 1268**.

Directors: Professor Robert Stockley, Professor Brendan Delaney
Hosted by: University Hospital Birmingham NHS Foundation Trust

Birmingham and the Black Country Comprehensive Local Research Network is part of the National Institute for Health Research and the UK Clinical Research Network



We wish you success on completing your research.

Yours Sincerely,

A handwritten signature in blue ink, appearing to read 'Susie Fisher', written over the closing 'Yours Sincerely,'.

Susie Fisher
CLRN RM&G Operational Manager (Consortium)
BBC CLRN RM&G Consortium

Documents Enclosed:

- (1) RM&G Permission Letter
- (2) Standard Conditions of RM&G Permission for the BBC CLRN RM&G Consortium & RM&G Reporting Form for Research Incidents

Scanned copy of Documents sent to:

Dr G I Hackett - Chief Investigator
Chris Zishiri - R&D Lead for BEN PCT

West Midlands (South) Comprehensive Local Research Network
CLRN Office
Fourth Floor Rotunda (ADA40017)
University Hospitals Coventry & Warwickshire NHS Trust
University Hospital
Clifford Bridge Road
Coventry
CV2 2DX

19th November 2009

Dr Trevor Gooding
Atherstone Surgery
1 Ratcliffe Road
Atherstone
CV9 1EU

Dear Dr Gooding,

Project Title: Clinical and Biochemical Improvement in Type 2 Diabetic Parameters Men with Symptomatic Testosterone Deficiency Syndrome (TDS). A Double Blind, Placebo Controlled Study of Depot Testosterone Undecanoate (NEBIDO) versus Placebo.

R&D Ref: WAR230909
REC Ref: 08/H1208/30

I am pleased to inform you that the R&D review of the above project is complete and has been formally approved to be undertaken at Warwickshire Primary Care Trust. Your research activity is now covered by NHS indemnity as set out in HSG (96) 48, and your trial has been entered onto the Trust's database.

The following documents were reviewed:

- **Protocol** 23rd May 2008
- **Patient Information Sheet** 12th July 2008
- **Consent Form** 12th July 2008
- **R&D NRES Application Form** Lock Code: AB/137541/1 Signed 27th May 2008
- **R&D Site Specific Information Form** Lock Code: 3702/64558/6/832/32571/152294 Signed 1st October 2009
- **NRES Approval Letter** Approval letter 5th August 2008
- **MHRA Notice of Acceptance** Approval Letter 9th May 2009
- **International Index of Erectile Function (IIEF)[115] Questionnaire**
- **Hospital Anxiety & Depression Scale – Scoring Sheet**
- **AMS Questionnaire**
- **CV Dr Geoff Hackett**
- **CV Dr Trevor Gooding**

Your responsibilities are set out in the attached agreement, which must be signed and returned to the R&D Office. You should keep a copy for your records.

All research must be managed in accordance with the requirements of the Department of Health's Research Governance Framework (RGF) and to ICH-GCP standards. In order to ensure that research is carried out to these standards, the Trust employs the services of an external monitoring organisation to provide assurance. Your study may be randomly selected for audit at any time, and you must co-operate with the auditors.

The duration of Trust approval extends to the date specified in the NRES application form. Action may be taken to suspend Trust approval if the research is not run in accordance with RGF or ICH-GCP standards, or following recommendations from the auditors. Research must commence within two years of the REC approval date, and within six months of R&D approval.

I wish you well with your project. Please do not hesitate to contact me should you need any guidance or assistance.

Yours sincerely



Luke Chaplin
R&D Facilitator

Enc: PI agreement

Cc: Geoff Hackett, Chief Investigator