



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (*Barrie*)

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Site Information

Site location

LMC Diabetes & Endocrinology (Barrie)
5 Quarry Ridge Road (suite 306)
Barrie, Ontario
L4M7G1

Contact Information:

705-737-0830 phone
705-737-0679 fax
800-701-ENDO (3636) Toll Free
barrieresearch@lmc.ca email

Specific clinical studies of interest

- *Type 1 & Type 2 Diabetes Mellitus*
- *Diabetes Complications - Neuropathy, Nephropathy, and Retinopathy*
- *Lipid Disorders*
- *Obesity*
- *Osteoporosis*
- *Hypertension*
- *Cardiac & Diabetes Prevention*
- *Women's Health*

Phase 2 - 4 Experience

Description of site

- *Private Clinic*
- *Ministry of Health Funded Diabetes Education Center*
- *Private Clinical Research Centre*

Memberships

- *Member of the Society for Clinical Research Sites (SCRS)*

Number of studies capable per site

6 enrolling studies with 4 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 6 years

Has the site been audited?

- No FDA audit
- No Health Canada audit
- No Sponsor audit

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Emergency response

- Royal Victoria Hospital (<.5 km from site)
- All staff are CPR certified annually

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Study Staff

Principal Investigator

Hani Ghalib Alasaad MBBS, DABIM, FRCPC, FACP, FACE

- 2 year research experience
- >6 clinical trials: Endocrinology &Metabolism

Sub Investigators

Suzan Abdel-Salam MD

- 6 years research experience
- > 20 clinical trials: Endocrinology &Metabolism

Vanessa Davies, BSc, CCPA

- <1 year research experience
- > 3 clinical trials: Endocrinology &Metabolism

Investigator Accountability

20% research, 80% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

| | | |
|-----------|---------------------------------------------------|--------------------------------------------------------------------------------|
| 1989-1990 | Rotating Internship | King Khalid University Hospital and affiliated hospitals, Riyadh, Saudi Arabia |
| 1990-1994 | Residency in Internal Medicine | Security Forces Hospital and Riyadh Medical Complex, Riyadh Saudi Arabia |
| 1994-1997 | Residency in Internal Medicine | Dalhousie University affiliated hospitals, Halifax, Nova Scotia, Canada |
| 1997-1999 | Fellowship in Endocrinology Diabetes & Metabolism | Dalhousie University affiliated hospitals, Halifax, Nova Scotia, Canada |

Appointments

| | | |
|--------------|----------------------------------------|---------------------------------------------------------------------------------------------------|
| 2012-present | Associate, Endocrinologist | LMC Diabetes & Endocrinology |
| 2000-2012 | Consultant Internist / Endocrinologist | Division of Endocrinology, Department of Medicine, Security Forces Hospital, Riyadh, Saudi Arabia |
| 1999-2000 | Senior Registrar | Security Forces Hospital, Riyadh, Saudi Arabia |

| | | |
|-----------|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1997-1999 | Fellow in Endocrinology, Diabetes and Metabolism | Victoria General Hospital, Halifax Infirmary, Queen Elizabeth II Health Sciences Center, Camphill Medical Center and Abby J. Lane Center at Dalhousie University, Halifax, Canada |
| 1996-1997 | Senior Resident in Internal Medicine | Victoria General Hospital, Halifax Infirmary and Camphill Medical Center, Dalhousie University, Halifax, Canada |
| 1994-1996 | Junior Resident in Internal Medicine | Victoria General Hospital, Dalhousie University, Halifax, Canada |
| 1990-1994 | Resident in Internal Medicine | Security Forces Hospital and Riyadh Medical Complex, Riyadh, Saudi Arabia |
| 1989-1990 | Rotation Intern | King Khalid University Hospital, Riyadh, Saudi Arabia |

3 Patient Population and Recruitment

Number of patients

>110,000 for the database plus an additional 20,000 per year and growing

Capability of screening database

Yes - able to note medical history, medications, lab values and consented interest in research

Catchment area

Barrie, Innisfil, Midland, Collingwood, Orillia, Bradford, Newmarket, Alliston, Wasaga, Stayner, Meaford & Thornburry

How are subjects recruited to meet the agreed upon targets?

- Patient database
- GP & Specialist referral network
- Diabetes triage - rapid assessment for newly diagnosed drug naive and metformin only patients failing orals requiring addition of OHA's or insulin initiation
- Advertising - radio, newspaper, central toll free number and capability of central ad campaigns for all LMC sites
- Public forums & expos
- Community involvement - Pharmacy days, and local presentations

4 Ethics

Ethics committee (local or central)

- Central Ethics only
- Worked with IRB Services, Schulman, Quorum, WIRB, Veritas, Canadian Shield, Optimum, etc.

Informed consent process

- See LMC Diabetes & Endocrinology SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA implemented

5 Facilities

Equipment available

- Refrigerated centrifuge (calibrated yearly)
- ECG machine (Brentwood software) - calibrated daily
- 330 kg weight scale (calibrated every 6 months)
- 1 x -20 freezers
- 1 x fridge for study medication purposes only
- Manual and automatic blood pressure devices
- Epi-pen and benedryl
- Able to do PK analysis, injections & meal tolerance tests

Office hours

- Monday - Friday (7:30 am - 6:00 pm)
- Weekends as needed

Monitoring space

- 1 room dedicated to monitoring
- Phone, analog, wireless and broadband access

LMC Diabetes & Endocrinology SOP

- ERB & HC reviewed and approved

Source documents

- LMC specific templates for source creation and study specific logs

Drug accountability and storage

- Secured and Locked Drug Cabinets, Medical Fridge and Freezer
- Temperature monitored daily (min, max and average temperatures)
- Sensaphone (remote monitoring, early detection system)

eCRF experience

- *INFORM*
- *INET*
- *RDC*
- *ORACLE*
- *PHOSCO*
- *Medidata*

IVRS experience

- Clinphone
- S Clinica
- ICON
- Fisher Clinical Services
- Impala

Data storage

- In house:
 - Lead study coordinator's office
 - Paper charts / Electronic medical records
- Long term storage:
 - Iron Mountain x 25 years
Address: Records Management Division
70 Talman Court
Concord, Ontario L4K 4L5
1-877-840-2111

6 Contract

Sites usual overhead

- 30% overhead

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Director of Research: Karri Venn RD, CDE, CCRC, PMP
Email: karri.venn@lmc.ca,
Phone: 647 274-4133 cell

Regulatory Documentation

- Regulatory & Clinic Specialist: Natalie Gibbs
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