Site Information

Site location
LMC Diabetes & Endocrinology (Calgary)
5940 MacLeod Trail SW (Suite 102)
Calgary, Alberta
T2H 2G4

Contact Information:
403 288-3224 phone
403 288-6409 fax
800 701-ENDO (3636) Toll Free
calgaryresearch@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
➢ Private Clinical Research Center

Memberships
➢ Member of the Society for Clinical Research Sites (SCRS)

Number of studies capable per site
4-5 enrolling studies with 5-6 maintenance studies

How long has the site been involved in clinical research?
Site has been doing research for 16 years

Has the site been audited?
➢ No FDA audit
➢ Health Canada audit in December 2009 - Compliant with minimal observations
➢ Sponsor audits - Had positive findings
Emergency response
- Rockyview General Hospital - 5 km from site
- All staff are CPR certified annually

2 Study Staff

Principal Investigator
Stuart Ross MB, CH.B, FRACP, FRCP
- 17 + years research experience
- > 150 clinical trials: Endocrinology & Metabolism

Sub Investigators
Ronnie Aronson MD, RRCPC, FACE
- 16 + years research experience
- > 200 clinical trials: Endocrinology & Metabolism

Akshay Jain MD
- 3 years research experience
- < 9 clinical trials: Endocrinology & Metabolism

Investigator Accountability
20% research, 80% clinic

Investigator’s Education and/or Academic Appointments
Speciality Areas: Endocrinology & Metabolism

Education
1965 M.B. Ch.B - Medicine Otago University, Dunedin, New Zealand
1971 MRACP Member Royal Australasian College of Physicians
1974 FRACP Fellow Royal Australasian College of Physicians
1980 FRCP(C) Canada

Appointments
1966-67 Rotating Internship and Residency, Auckland Hospital Board
1968-70 Senior Resident in Endocrinology, Auckland Hospital Board
1970-72 Bank of New Zealand Research Fellow in Carbohydrate Metabolism, Auckland, New Zealand, Dr. H. K. Ibbertson (Professor of Endocrinology)
1972-75 Canadian Medical Research Fellow, McGill University, Montreal (Dr. J. Dupre)
1975-81 Assistant Professor of Medicine - University of Calgary
1975-91 Director, Diabetes Education and Treatment Centre Foothills Provincial Hospital
1981-92 Associated Professor of Medicine
1992-current Clinical Professor of Medicine
1994-current Director, Calgary Metabolic and Education Research Centre
2009-current Associate, Endocrinologist, LMC Diabetes & Endocrinology
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 and interest in research

Catchment area
Calgary

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)
Local ethics only – Health Research Ethics Board of Alberta – Clinical Trials Committee (HREBA-CTC)

Informed consent process
- See LMC Diabetes & Endocrinology SOPs
- GCP/ICH Compliant

Confidentiality
- PIPEDA implemented
- Alberta Health Act

5 Facilities

Equipment available
- Refrigerated and ambient centrifuge (calibrated yearly)
- ECG machine (calibrated yearly)
- 330 kg weight scale (calibrated every 6 months)
- 1 x -20 freezers
- 1 x medical fridge for study medication purposes only
- Manual and automatic blood pressure devices
Able to do PK analysis, injections & meal tolerance tests
Thermometers (fridge, freezer & drug rooms) - calibrated yearly
Data loggers - temperature measured every 10 minutes - calibrated yearly

Office hours
- Monday - Friday (7:30 am - 4:00 pm)
- Weekends as needed

Monitoring space
- 1 room dedicated to monitoring - can accommodate 2 monitors
- 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
- RAVE

IVRS experience
- Clinphone
- S Clinica
- ICON
- Fisher Clinical Services
- Impala
- Almac

Data storage
- In house: Lead study coordinator's office, paper charts, electronic medical records
- Long term storage: Iron Mountain x 25 years
  Address: Unit 20 5350 86 Ave.SE
  Calgary, AB T2C 4L7
  Records Management Division
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
  Email: natalie.gibbs@lmc.ca
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