Ongoing and future studies on vasculitis in Canada

1st CanVasc meeting – Toronto – 10 June 2011
Vasculitis trials and studies

• Active in Canada
  – ARCHIVE
  – PACNS registry
  – VCRC longitudinal study
  – GCA and MRI (McMaster – Khalidi)
  – VCRC AGATA GCA/TA
  – EUVAS/VCRC/International PEXIVAS
  – VCRC one-time DNA + C. Siminovitch (Toronto)
VCRC longitudinal study

- Hamilton, Toronto
- GCA, TA, PAN, MPA/GPA, CSS

- Visits every
  - 3 months for 2 years then yearly
  - Every year
### VCRC Longitudinal Study

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**Note:** The table above provides the number of protocols for each category.
AGATA LVV

- VCRC 5523 (and 5522 for GPA)
- CTLA4-Ig
- 2 Hamilton
- 1 Toronto
- Total 39
- 33+33 Needed
McMaster’s GCA / MRI study

• Dr. Khalidi
• Dr. Clements-Baker
• Dr. Rebello
• Dr. Ioannidis

PEXIVAS

a RCT of plasma exchange and glucocorticoid dosing in ANCA associated vasculitis

On behalf of the PEXIVAS Trial Group
Eligibility

Inclusion

• New or Previously diagnosed GPA or MPA
• ANCA + (by ELISA)
• Current “severe” manifestation
  – GN with eGFR <50 ml/min
  – Lung hemorrhage
• Informed Consent or Deferred Consent

Exclusion

• <18 years old (<15 in peds centres)
• Concomitant anti-GBM or other non-AAV vasculitis
• Pregnant
• Received significant therapy for this presentation already
  – >1 IV dose or 2 weeks CYC
  – >1 dose RTX within 1 month
  – >14 days pred >30 mg/day
• Likely has ESRD already
• PLEX or other trial therapy mandated or contraindicated.
Severe AAV

Cyclophosphamide
Or Rituximab

Adjunctive Plasma Exchange
Standard-Dose GC
Reduced Dose GC

No Plasma Exchange
Standard-Dose GC
Reduced Dose GC

Follow-Up
ESRD
Death
Study follow-up

• Common study termination point

• Minimal follow-up = 2 years

• Recruitment over 5 years
  → Maximal follow-up = 7 years
Outcomes

• Primary
  – Composite of ESRD or death

• Secondary
  – Sustained remission at 12 months
  – Adverse events
  – Health related quality of life
  – ESRD
  – Death
Canada (6 June 2011)
2 from St Joseph's Hospital, Hamilton, Ontario, Canada
2 from University of Alberta, Edmonton, Alberta, Canada

London, ON
St Michael’s, ON
VCRC Genetic Repository
One-Time DNA Protocol

• VCRC 5510
• Aims
  – Collect clinical data and DNA on patients with GCA, TA, PAN, GPA, MPA, CSS
  – Discover genetic markers that increase the risk of developing vasculitis
  – Discover genetic markers linked with certain symptoms of vasculitis
• 93/1,300 patients so far
VCRC Genetic Repository
One-Time DNA Protocol

- GWAS
- Candidate-gene studies and fine-scale genotyping

- 2 x 10ml vials (purple top tubes)
- Sent to BU Genetics Lab. (code bar)

- Local REB approval
Patients reported outcome studies / driven surveys

- VCRC Reproductive Health in Men and Women with Vasculitis
VCRC patient registry

http://rarediseasesnetwork.epi.usf.edu/vcrc/index.htm

> 2,000
We have a brand new on-line research study open that might be of interest to you! Please read below for more information.

Dear Jennifer Schaubie Lloyd,

You are invited to participate in an on-line research study being conducted by the Vasculitis Clinical Research Consortium (VCRC) under the direction of Dr. Megan Clowse, from Duke University Medical Center and VCRC Investigators at the University of South Florida.

Purpose and Background

The purpose of this study is to learn about reproductive health, including fertility and pregnancies, in people with vasculitis.

Who Can Take This Survey?

Both men and women with vasculitis age 18 and older can participate in this study.

What This Study Involves

This study consists of an online survey. You will be asked to provide answers to a series of questions related to your reproductive health and vasculitis. The consent form explains the research study and your part in the study. If you decide to participate in this confidential research you will be directed to the survey after you read the consent form and choose that you would like to participate. The survey should take about 20-30 minutes of your time.

If you want to participate in this study, please click here.

The Rare Diseases Clinical Research Network will make every effort to enroll all the patients we can, but we cannot make any guarantees that we will be able to enroll everyone in a particular study who wants to participate. Participation in research studies is voluntary. Deciding not to participate in a research study does not affect your ability to receive care at any of our Clinical Centers or from other physicians.

Visit us at: www.RareDiseasesNetwork.org/vasculitis

Stay Informed!

We want to keep you informed with the latest news and information. Keeping your contact information up to date can be done quickly and easily on the Web:

Click Here to Update Your Information

About the VCRC

The Vasculitis Clinical Research Consortium (VCRC) is an integrated group of academic medical centers, patient support organizations, and clinical research resources dedicated to conducting clinical research in different forms of vasculitis and improving the care of patients with vasculitis.

The Vasculitis Clinical Research Consortium is part of the National Institutes of Health’s Rare Diseases Clinical Research Network. The VCRC continues to grow and is working on several new research projects concerning vasculitis. Check back with the VCRC website regularly for updates:

www.RareDiseasesNetwork.org/vasculitis

467 responded after 3 email campaigns
VCRC Reproductive Health in Men and Women with Vasculitis

• Online questionnaire
  – 16 pages
  – Electronic ICF

• Aims
  – Compare infertility rate with or without CYC
  – Compare pregnancy complication rate before vs after vasculitis onset
Patients driven survey / reported outcome studies

- VCRC Reproductive Health in Men and Women with Vasculitis
- VCRC Pregnancy registry
- VCRC patient illness perception
- Edmonton study
Trials and studies

• Projects in Canada
  – Patients driven survey
  – DCVAS
  – CanVasc database/cohort
  – Sherbrooke practice survey
  – Canadian recommendations for diagnosis, management and follow-up
DCVAS

• Each center willing to participate to contact Rashid Luqmani
dcvas@ndorms.ox.ac.uk

• Each center will need local REB approval

• US $15 per patients with full set of data
  (US $10 if paper sheet)
CanVasc database/cohort

• 2 options
  – Paper record form to send to CanVasc
  – Locally stored Access® CanVasc database (duplicate → synchronizable)

• Every center/MD can participate
  – Local REB approval
  – Focus on CSS and Takayasu

• Retrospective and prospective
Important ongoing trials and studies outside Canada

- VCRC AGATA GPA 5522
- CORTAGE
- CHUSPAN2
- REMAIN
- MYCYC
- MAINRITSAN
(Possibly) important study projects outside Canada

- Rituximab for maintenance (EUVAS)
- Gusperimus in AAV
- Mepolizumab in CSS
(Possibly) important study projects outside Canada

- Rituximab for maintenance
- Gusperimus
- Mepolizumab
- Apremilast
- Belimumab
- Anti-IL6 receptor
- Complement inhibitors
Conclusions

• Enroll patients in cohorts/studies/trials!!
  – Rare diseases
  – New treatments
  – Drug cost coverage

• Don’t jump over the gun!