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Learning to live better with lupus: the Health Improvement and Prevention Program (HIPP) in systemic lupus erythematosus

Submission date	Recruitment status	[ ] Prospectively registered
16/06/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/06/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/02/2019	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.canios.ca/About_canios_studies_HIPP.aspx?AspxAutoDetectCookieSupport=1

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00188357

Secondary identifying numbers
MCT-82939

Study information

Scientific Title
The Health Improvement and Prevention Program (HIPP) in systemic lupus erythematosus: a randomised, cross-over, open-label efficacy study

Acronym
HIPP

Study objectives
1. The Health Improvement and Prevention Program (HIPP) will improve the physical component (PCS) and mental component (MCS) summary scores of the 36-item short form (SF-36) health status survey by an average of 4 points
2. HIPP will reduce the Framingham 8-year projected risk of cardiovascular disease (CVD) in persons with systemic lupus erythematosus (SLE) by 20%
3. HIPP will improve the flow mediated dilatation (FMD) of brachial arteries significantly

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Board of the University Health Network, Toronto approved on the 13th January 2004 (ref: 03-0605-A)
2. Research Ethics Board of McGill University approved on the 1st December 2006 (ref: 03-034)
3. Research Ethics Board of the University of Western Ontario approved on the 31st January 2008 (ref: 13732)

Study design
Randomised, cross-over, open-label efficacy study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Patient information material can be found at http://www.canios.ca/About_canios_studies_HIPP.aspx?AspxAutoDetectCookieSupport=1

Health condition(s) or problem(s) studied
Systemic lupus erythematosus

Interventions
Experimental interventions:
1. Non-drug coronary artery risk reduction in the setting of lupus measured at three months for one year followed by every six months for one year
2. Non-drug osteoporosis risk reduction in the setting of lupus measured at three months for one year followed by every six months for one year
3. Non-drug exercise in the setting of lupus measured at three months for one year followed by every six months for one year
4. Non-drug mindfulness based stress reduction in the setting of lupus measured at three months for one year followed by every six months for one year

Control intervention:
Usual care for 12 months.

Added 26/02/2009:
Secondary sponsor details:
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c/o Dr. Paul Fortin
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
36-item short form health survey physical and mental component summary scale (SF-36 PCS and MCS) scores, coronary disease risk reduction profiles and flow-mediated dilatation of the brachial artery yearly for two years.

Secondary outcome measures
1. Bone health improvement: yearly while on prednisone; every two years for all others
2. Adherence to treatment: every three months for one year and every six months for one year

Overall study start date
01/08/2003

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Systemic lupus erythematosus according to American College of Rheumatology (ACR) criteria
2. 18 years or older
3. Female
4. Able to read and English or French

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
310 patients to enroll (to achieve 260 completers)

Key exclusion criteria
1. History of angina
2. Myocardial infarct
3. Cerebral vascular accident
4. Trans-ischaemic attack
5. Peripheral vascular disease
6. Osteoporosis with fracture confirmed by radiology
7. Pregnant or planning within two years
8. Cancer (if cancer-free for five years then eligible)

Date of first enrolment
01/08/2003

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Canada

Study participating centre
UHN - TWH Research Institute
Toronto, Ontario
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Sponsor information

Organisation
University Health Network (Canada)

Sponsor details
200 Elizabeth Street
Toronto, Ontario
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Sponsor type
University/education

Website
http://www.uhn.ca/index.htm

ROR
https://ror.org/042xt5161

Funder(s)

Funder type
Research organisation

Funder Name

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration