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Palpable Lymphadenopathy In Clinical Practice

Submission date 23/03/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 04/05/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/04/2013	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Palpable Lymphadenopathy In Clinical Practice: a multi-centre, prospective, case-control study

Acronym
PLICP

Study objectives
In adult patients with palpable lymphadenopathy are there any clinical or ultrasound factors indicative of malignancy? What is the correlation between those factors? How sensitive and specific are they in comparison to the pathologic examination of the biopsied lymph node for establishing a diagnosis of malignancy?

The rationale behind this study is that malignant and benign lymphadenopathies have specific quantifiable identifiers. We hope that we will find and quantify signs form clinical and ultrasound examination of the patients with limphadenopathies that would point to a malignant or benign cause of the lymphadenopathy. The main purpose for this study is to shorten the average time to diagnosis for patients with lymphadenopathy and to ascertain whether inexpensive route to the diagnosis. This study should yield a decision making algorithm for palpable lymphadenopathies. This study will attempt to map the spread of tumors from different regions to their regional lymph nodes.

As of 27/03/2012, the anticipated end date of trial has been updated from 01/04/2012 to 01/04/2013.

As of 03/04/2013, the anticipated end date of trial has been updated from 01/04/2013 to 01/04/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Clinical Center Nish Ethics Board on 01/02/2011 ref: approval number 2280/32

Study design
Multi-centre prospective case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Palpable lymph node enlargement

Interventions
1. This is an observational study and all interventions are decided upon by the patients physician and are not influenced by the study design.
2. This study will collect data from clinical, ultrasound and intraoperative examination of the patient and his enlarged lymph nodes
3. This study also collects data from the pathologic examination of the biopsied lymph node
4. The data regarding the lymphadenopathy will be collected by the patients physicians during the time of the exam and inputed in pre-made forms which will then be stored in databases for statistical testing at the end of the study
5. The two primary arms will be benign and malignant palpable lymphadenopathy
6. Secondary (optional) arms are non-palpable but peripheral lymphadenopathies obtained from:
6.1. Incidental radiologic findings
6.2. Planned sentinel node biopsies
6.3. Planned region dissections for primary disease staging
7. For the purpose of this study peripheral lymph nodes are:
7.1. Submandibular,
7.2. Submental
7.3. Preauricular
7.4. Retroauricular
7.5. Occipita
7.6. Upper, middle and lower jugular
7.7. Prelaringeal
7.8. Posterocervical
7.9. Suboccipital
7.10. Supraclavicular
7.11. Infraclavicular
7.12. Middle and lower axillary
7.13. Epitrochlear
7.14. Surface inguinal
7.15. Deep inguinal
7.16. Popliteal
8. The primary analysis will attempt to find clinical and ultrasound parameters correlating with a pathologic diagnosis of malignancy and those correlating with a benign cause
9. The statistician will decide on the statistical methods that will be used when the study ends and the database is reviewed

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Determining the correlation between the parameters collected in our study through clinical and ultrasound examination with the:
1. Diagnosis of malignancy established by pathologic examination of the biopsied lymph node
2. Diagnosis of a benign disease established by pathologic examination of the biopsied lymph

node
3. Diagnosis of a benign cause of lymphadenopathy established by spontaneous reversal of lymphadenopathy sustained over 3 months
4. The parameters collected are:
4.1. Clinical exam and history: age, sex
4.2. Node location and external size (2 dimensions)
4.3. Presence of splenomegaly
4.4. Pain on palpation
4.5. Lymph node texture (subjective)
4.6. Complete blood count (CBC)
4.7. Lactate dehydrogenase (LDH)
4.8. Erythrocyte sedimentation
4.9. Presence of night sweats
4.10. Pruritus
4.11. Unexplained loss of weight, or unexplained fevers
4.12. History of malignant diseases
4.13. Presence of any "supicious" lesion during a whole body physicial exam
5. Ultrasound:
5.1. Size, location and number of enlarged lymph nodes, echogenicity (hyper, hypo, hilar, diffuse, perinodal, localised)
5.2. Demarcation from surrounding tissue
5.3. Presence of necrosis
5.4. Vascularity (avascular, hillar, diffuse, peripheral, localised)
5.5. Calcifications
5.6. Presence of splenomegaly
5.7. Resistive and pulsatile index
6. Pathologic examination:
6.1. Size of lymph node
6.2. Microscopic morphology (normal-resembles lymph node, changed does not resemble a lymph node)
6.3. Presence of granulomas, necrosis or calcifications
6.4. Presence of metastasis and size
6.5. Final diagnosis

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/04/2011

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. Patients with palpable lymphadenopathy
2. Patients with radiologically proven, but still not palpable, peripheral lymphadenopathy
3. Patients with a sentinel node biopsy or regional dissections as part of their staging

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
Minimum number: 100 malignant and 100 benign

Key exclusion criteria
1. Patients unable or unwilling to give consent
2. Patients younger than 18

Date of first enrolment
01/04/2011

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
Serbia

Study participating centre
Klinika za hematologiju i kliničku imunologiju
Ni
Serbia
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Sponsor information

Organisation
Serbian Medical Society (SLD Ni, gradska podrunica) (Serbia)

Sponsor details
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18000

Sponsor type
Other

Website
http://www.sldnis.org.rs/

Funder(s)

Funder type
Research organisation

Funder Name
Serbian Medical Society (Srpsko Lekarsko Drutvo) (Serbia)

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