

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

Contact name

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Additional identifiers

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 from clinical and ultrasound examination of the patients with lymphadenopathies 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.

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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

Primary study design

Observational

Study design

Multi-centre prospective case-control study

Study type(s)

Diagnostic

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(s)

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 "suspicious" lesion during a whole body physical 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, hilar, 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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

18000

Sponsor information

Organisation

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

Funder(s)

Funder type

Research organisation

Funder Name

Serbian Medical Society (Srpsko Lekarsko Drutvo) (Serbia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration