



Protocol of a Thesis for partial fulfillment of M.D. degree of Orthopedic Surgery

**Title of the protocol: Total Knee Arthroplasty in conjunction with
intra-operative Genicular Nerve Radio-Frequency Ablation,
A randomized controlled clinical trial**

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What is already known about this subject?

What does this study add?

Total knee arthroplasty (TKA) is considered the gold standard management for advanced knee osteoarthritis, however around 20% of the patients still complain of persistent knee pain after the operation¹. This study will add a new concept of combining genicular nerve radio-frequency ablation (GNRFA) with TKA in a hypothesis to improve functional outcome, post-operative pain and quality of life.

1.Introduction/Review

Total knee arthroplasty is a very common operation, and its incidence is believed to increase furthermore in the near future². That's why there are a lot of studies focused on improving the patient's satisfaction rate, while the unsatisfied patients remain to vary from 10%-30% without any noticeable complications³. Early post operative rehabilitation and fast track protocols showed improvement in functional outcome and pain relief but are still hindered by the patients compliance⁴. The idea of implementing genicular nerve radio-frequency ablation in combination with TKA rose when GNRFA showed significant improvement in patients with chronic knee osteoarthritis, studies showed pain relief up to 67% at the first 3 months, yet alone it has a very slim indications as it addresses only the biological aspect of the knee osteoarthritis without resolving the mechanical problem that will continue to progress over time⁵. Other studies showed positive outcome of GNRFA in cases of chronic knee pain after TKA^{6, 7}.

Given that data, combining GNRFA with TKA might give the patient a better chance to proceed with early rehabilitation programs improving the functional outcome, while decreasing postoperative pain is also considered an important factor of patients' satisfaction and quality of life enhancement.

2.Aim/Objectives

To compare between conventional Total Knee Arthroplasty (TKA) and Total Knee Arthroplasty (TKA) combined with intra-operative Genicular Nerve Radio-Frequency Ablation (GNRFA), concerning post-operative functional outcome and pain scores in patients with advanced knee osteoarthritis.

3.Methodology

- **Type of the study:** Randomized controlled clinical trial
- **Study setting:** Ain Shams University hospitals
- **Study period:** 24 months
- **Study population:** Patients with advanced knee osteoarthritis
 - Inclusion criteria:**
 - Both sexes
 - Age from 50-80 years old
 - Exclusion criteria:**
 - Patients unfit for surgery
 - Patients underwent previous GNRFA
- **Sampling method:** Convenient sample
- **Sample size:** 70 knees will be randomly divided by a computer-generated sequence in to 2 groups:
 - Group A (≈35 knees): will undergo TKA
 - Group B (≈35 knees): will undergo TKA combined with GNRFA
- **Ethical considerations:** will be followed by obtaining the hospital research/ethics committee approval and written informed consents from the patients.

- **Study tools:**
 - **Preoperative diagnosis and evaluation:**
 - **Clinical Evaluation:**
 - History
 - General examination
 - Local examination (pre-operative)
 - **Radiological Evaluation:**
 - Plain X-ray antero-posterior standing view of the diseased knee.
 - Plain X-ray lateral view of the diseased knee.
 - **Laboratory investigations:**
 - Routine preoperative lab investigations
 - **Operative technique:**

Patients will be operated using standard mid-vastus approach, conventional GNRFA
 - **Post-operative management:**
 - Proper antibiotic and standardized analgesics protocol will be given post-operative
 - Prophylaxis against DVT
 - Post-operative x-rays will be done, Plain X-ray antero-posterior and lateral view of the operated knee.

○ **Follow up strategy:**

Patients will be reviewed after 2 weeks to check their wounds and for sutures removal, then the follow up will be every month in the first 6 months then every 3 months till the end of the study (2 years). The follow up will include:

➤ **Clinical and functional assessment:**

- Oxford knee score to assess the function.
- Visual analogue scale (VAS) to assess pain.
- Emotional acceptance/ Patient satisfaction.

➤ **Radiological assessment:**

Plain X-ray as described before at every follow up visit.

- **Statistical Analysis:** Statistical package for social science (SPSS 15.0.1 for windows; SPSS Inc., Chicago, IL, 2001). Data will be presented as Mean and Standard deviation (+/-SD) for quantitative parametric data, and Median and Interquartile range for quantitative non-parametric data. Frequency and percentage will be used for presenting qualitative data. Suitable analysis will be done according to the type of data obtained. $P < 0.05$ will be considered significant.
- **Statistical package:** data entry and statistical analysis of the collected data will be performed using a reliable software program.

4. References

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