



# 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 operation<sup>1</sup>. 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 future<sup>2</sup>. 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 complications<sup>3</sup>. Early post operative rehabilitation and fast track protocols showed improvement in functional outcome and pain relief but are still hindered by the patients compliance<sup>4</sup>. 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 time<sup>5</sup>. Other studies showed positive outcome of GNRFA in cases of chronic knee pain after TKA<sup>6, 7</sup>.

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 ( $\approx$ 35 knees): will undergo TKA
  - Group B ( $\approx$ 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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