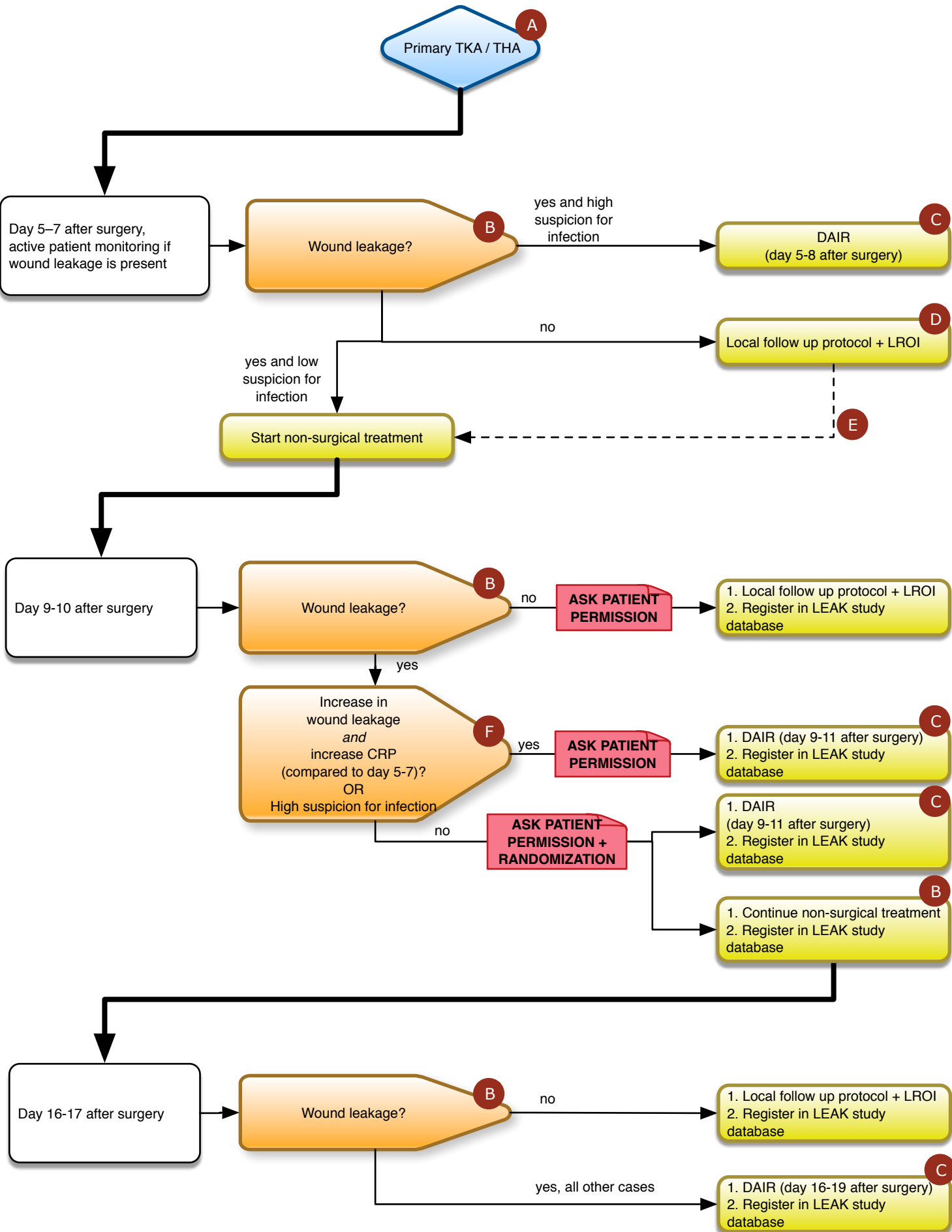


# LEAK study flowchart



**Note A:**

- Patient receives "Basic information flyer LEAK study" at time of indication for primary TKA / THA.

**Note B:**

- Register parameters in local electronic patient file in a standardized manner.
- Determine CRP.
- Determine LEAK class =
  - LEAK Class 0, dry
  - LEAK Class 1, mild: stripe of blood in wound dressing or ≤ 2x2 cm in gauze per 24 hr
  - LEAK Class 2, moderate: > 2x2 cm in gauze and no need for >1 absorbent gauze exchange per 24 hr
  - LEAK Class 3, severe: need for >1 absorbent gauze exchange per 24 hr
- Describe clinical parameters = Redness, fever (Temp. ≥ 38.5 degrees Celcius), pain, swelling.
- Non-surgical treatment = relative rest (stop exercise, bed rest), wound care with sterile bandages, pressure bandage, hospital admission can be considered (not applicable at day 16).
- High suspicion for infection = Fever (Temperature > 38.5 degrees Celsius) + red indurated wound + pain.

**Note C:**

- DAIR (Debridement Antibiotics and Implant Retention) is done to clean the prosthesis and the wound.
- The components of DAIR are:
  - Wound opening
  - 1 culture of fluid deep to the fascia
  - Arthrotomy and than ≥4 deep tissue cultures (2 synovial, and ≥1 around both components of the joint prosthesis)
  - Antibiotics are started only *after* taking the cultures
  - Mobile parts (e.g. tibial insert, femoral head) are exchanged to make room for optimal debridement
  - Extensive debridement is done, i.e. resection of hematoma and necrosis and synovectomy
  - Thorough wound lavage with 3-6 litres of saline
  - It is advised to use scrub sponges to mechanically clean all visible prosthesis parts
  - Povidon iodine solution or chloorhexidin solution may be used
- Follow-up procedure after DAIR: wound LEAK class registration 2-3 times a week and CRP control 2-times a week. Culture results are registered and time to complete dry wound. In case of persistent wound leakage a second DAIR may be considered according to judgment of treating surgeon.

**Note D:**

- Patient receives "Patient information LEAK study" on day 5-7 after surgery.

**Note E:**

- If new wound leakage starts between day 5-7 and 9-10 after surgery, the patient is still eligible for randomization (at day 9-10). Perform DAIR in case of high suspicion for infection (see Note B).

**Note F:**

- If wound leakage is observed only at day 9-10 after surgery, the patient is still eligible for randomization (at day 9-10).
- Increase in wound leakage = increase of one class or more (see Note B for LEAK class).
- Increase in CRP = ≥ 25% increase compared to last previous CRP.
- High suspicion for infection = Fever (Temperature > 38.5 degrees Celsius) + red indurated wound + pain.

**ASK PATIENT PERMISSION**

Ask patient permission to use anonymized data for study purposes and record in patient file.

**ASK PATIENT PERMISSION + RANDOMIZATION**

- Ask patient permission to use anonymized data for study purposes and record in patient file.  
- The patient is randomized at this moment between DAIR (day 9-11 after surgery) and continued non-surgical treatment.