

# Evaluating the Safety and Efficacy of AMOR-1 as a Treatment for Hypocalcemia Associated With Hypoparathyroidism in Adults

NCT06547151

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Status	RECRUITING
Phase	Phase 2
Sponsor	Amorphical Ltd.
Enrollment	81 participants

## Key Eligibility Criteria

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### Inclusion (12)

- An understanding, ability, and willingness to fully comply with study procedures and restrictions.
- Ability to voluntarily provide written, signed, and dated informed consent as applicable to participants in the study.
- Adult males or females 18 or older (prior to screening). Those < 25 years old will be examined radiologically (Bone age X-ray of non-dominant wrist and hand) to ensure epiphyseal closure prior to enrollment into the study.
- Hypoparathyroidism patients, from any etiology, who are on currently available Standard of Care (SoC) e.g., calcium supplement and active vitamin D metabolite/analog.
- Oral calcium e 1000 mg QD above the normal dietary calcium intake

... and 7 more (see full listing online)

### Exclusion (19)

- Any disease that might affect calcium metabolism or calcium-phosphate homeostasis other than hypoparathyroidism, such as active hyperthyroidism, Paget's disease of bone, Type 1 or poorly controlled Type 2 diabetes mellitus (HbA1c > 9%), acromegaly, multiple endocrine neoplasia types I and II, Cushing's syndrome or disease, acute pancreatitis, malnutrition, recent prolonged immobility.
- Severe liver disease (Child-Pugh score >9) (US FDA, 2003) or hepatic transaminases (ALT and AST) > 3 times the upper limit.
- Severe renal insufficiency defined as estimated glomerular filtration rate (eGFR) < 30 ml/min/1.73 m<sup>2</sup>.
- Clinical history of symptomatic renal stones within the past 3 months. Subjects with asymptomatic renal stones are permitted.
- Poorly controlled short bowel syndrome, bowel resection, tropical sprue, celiac disease, ulcerative colitis, and Crohn's disease.

... and 14 more (see full listing online)

## Locations (8 total)

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Assuta Ashdod medical center, Ashdod, Israel, Israel  
Hadassah Ein Kerem Medical Center, Jerusalem, Israel, Israel  
Rabin Medical Center, Belinson Campus, Petah Tikva, Israel, Israel

... and 5 more locations

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<https://clinicaltrials.gov/study/NCT06547151>

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