KLARA

POLSKI OŚRODEK
TERAPII KOMÓRKOWYCH
I IMMUNOTERAPII

Wharton's Jelly MSC Therapy

An Experimental Clinical Pathway for Neurological and Ophthalmological Conditions

Comprehensive Patient & Clinical Guide

NotebookLM

The Clinical Pathway Blueprint



The Clinical Objective

- Evaluate allogeneic Mesenchymal Stem Cells (MSCs)
- Aim to improve clinical outcomes and restore lost functions
- Designed for neurological or ophthalmological diseases lacking causal treatments or failing standard therapies



The Experimental Reality

- Participation is strictly voluntary
- Direct health benefits are hoped for, but not guaranteed
- Results contribute to broader medical knowledge
- Patients may withdraw at any time without impacting standard diagnostic care

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The Clinical Pathway Blueprint

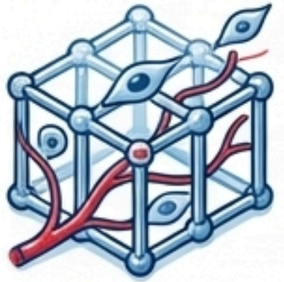


Wharton's Jelly MSCs



Immunomodulation

Regulates the immune system to actively limit biological aggression and inflammation directed against the patient's own tissues.



Direct Tissue Repair

Initiates direct, localized regenerative processes within specific target tissues in the neurological system or the eye.

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The Clinical Pathway Blueprint



1. Ethical Sourcing

Harvested from Wharton's jelly of healthy, full-term newborns. Explicit parental consent. Rigorous maternal blood screening. No embryonic cells used.



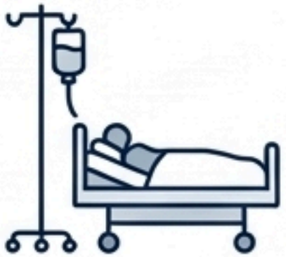
2. Lab Processing

Cultured in vitro at PBKM Cell Engineering Lab. Tested strictly for surface antigens, cell viability, and microbiological purity.



3. Secure Transport

Transported in sterile saline (under 24 hours) or via specialized cryo-transport directly directly to KLARA Medical Center.



4. Bedside Preparation

Precise thawing occurs directly at the patient's bedside to minimize any potential positive-temperature toxicity from cryoprotectants.

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The Clinical Pathway Blueprint

Inclusion Criteria

- ✓ • Ages 18 to 85 years old
- ✓ • Both male and female patients
- ✓ • Confirmed diagnosis of an untreatable neurological or ophthalmological condition

Exclusion Criteria

- ✗ • Pregnancy or breastfeeding (Strictly Prohibited)
- ✗ • Severe or acute organ damage
- ✗ • Infectious diseases (HIV, HBV, HCV, HPV)
- ✗ • Severe mental disorders or active malignancies
- ✗ • Unstable cardiovascular system
- ✗ • Allergy to Penicillin G

⚠ **Crucial Requirement:** Mandatory adherence to strict contraception protocols during the therapy.

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Administration Modalities



Intravenous (IV)

- Mandatory for 1st Injection & Standard for Neurological

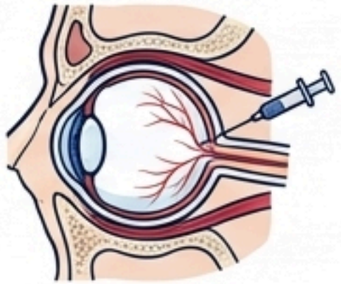
DMSO Status: Retained. Safely metabolized by the liver.



Intrathecal (Spinal)

Application: Select Demyelinating & Neurological conditions

DMSO Status: Strictly Washed Out to prevent closed-space toxicity.



Retrobulbar (Eye)

Application: Ophthalmological conditions

DMSO Status: Strictly Washed Out.

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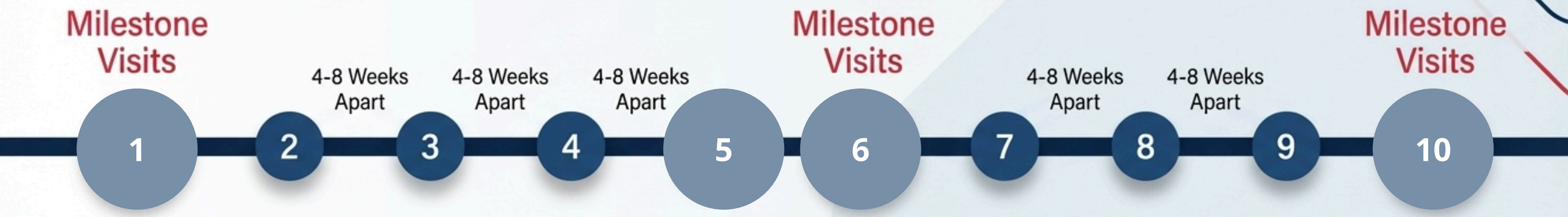
Clinical Protocol Timeline & Diagnostics



Every Visit (Nodes 2-5, 7-9)

- ✓ • Physical & Neurological exams
- ✓ • Vitals, EKG, blood/urine analysis
- ✓ • Adverse event monitoring & MSC Administration
- ✓ • **Neuro only:** Spirometry, Gait & Muscle force testing

Milestone Diagnostics (Nodes 1, 6, 10)

- • **Neurological:** Specialized EMG testing (ALS, MS, Dystrophies)
- • **Ophthalmological:** Tonometry, Slit lamp, Fundus, OCT optic nerve & ganglion, Angio OCT, Visual Field, Ishihara

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The Hospital Experience

Day 1: Admission

01



Admission to the KLARA ward. Initial vitals and pre-treatment baseline checks.

Day 2: Treatment

02



Bedside thawing of MSCs and primary administration (IV, Spinal, or Ocular). Observation phase begins.

Bedside **thawing of MSCs and primary administration (IV, Spinal, or Ocular). Observation phase begins.**

Day 3: Discharge

03



Final clinical evaluations and morning discharge.



Logistical Note: Therapy costs inclusively cover hospital accommodation for one parent, caregiver, or family member to stay alongside the patient during the entire 48-hour window.

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Transparent Risk Mapping: Clinical Pathways & Procedures

Mild / Temporary Risks

- Transient headache, fever, neck stiffness
- Leg pain, confusion, standing/walking difficulties
- Fatigue, state of feeling unwell
- Potential allergic reactions (rash, itching, hives)

Severe / Theoretical Risks

- Viral or bacterial transmission
- Sepsis due to involuntary bacterial infection
- DMSO (Cryoprotectant) toxicity
- Post-transfusion acute respiratory failure

Lumbar Puncture Specific Risks

- Post-operative headache, localized infection, or bleeding
- Lower limb numbness, radiculopathy, lumbar pain
- Extremely rare: Brain herniation (in cases of elevated intracranial pressure)

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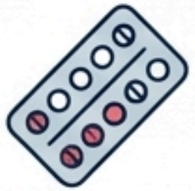
Pregnancy & Contraception Mandate

Participation is strictly prohibited for pregnant or breastfeeding women. Mandatory pregnancy testing is conducted prior to the experiment.

Women of Childbearing Potential (WOCBP) and male participants with WOCBP partners must utilize **TWO** reliable methods of contraception throughout the therapy (at least one must be a mechanical barrier).



Hormonal



Intrauterine Device



Double-Barrier



Strict Abstinence

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Logistics, Costs & Next Steps

01

Prepare Documents



Gather full medical records, Hepatitis B vaccination book, and lab results: HCV RNA (qualitative), Borrelia IgG/IgM (ELISA), anti-HBs, and HIV.

02

Submit for Qualification



Send complete package for preliminary verification to therapymsc@cm-klara.pl or via registered mail to Centrum Medyczne Klara (Częstochowa).

03

Financial Architecture



Un-refunded medical experiment. Costs are individualized based on disease, cell count, and route. All payments must be processed exclusively through a designated foundation or association (no direct patient payments).

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