KLARA
CENTRUM MEDYCZNE

Therapeutic Experiment for Neurological Diseases

An informational guide for the treatment of children using Wharton's jelly mesenchymal stem cells.

Jesteś w dobrych rękach

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Defining the therapeutic experiment and protecting patient rights

The Objective

A therapeutic experiment introduces new or partially tested diagnostic and therapeutic methods. It is strictly utilized when standard treatments have failed to improve the patient's clinical condition, aiming for a direct health benefit.

Patient Bill of Rights

- Participation is entirely voluntary.
- Patients have the right to withdraw at any time.
- Withdrawal will never affect standard diagnostic procedures and care.
- While personal health benefits are not guaranteed, the data helps advance medical knowledge for all patients facing the disease.

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Ethical and safe sourcing of Wharton’s jelly mesenchymal stem cells



The Source: Cells are strictly obtained from Wharton's jelly within the umbilical cords of full-term, healthy newborns.



The Process: Tissue is collected only after birth and umbilical cord clamping. The collection has zero impact on labor, delivery, or medical procedures for the mother and child.



The Ethical Standard: Explicitly excludes the use of human embryonic stem cells and human auditory cells. Donors undergo rigorous medical interviews and maternal blood testing to ensure zero transmission of infectious diseases.

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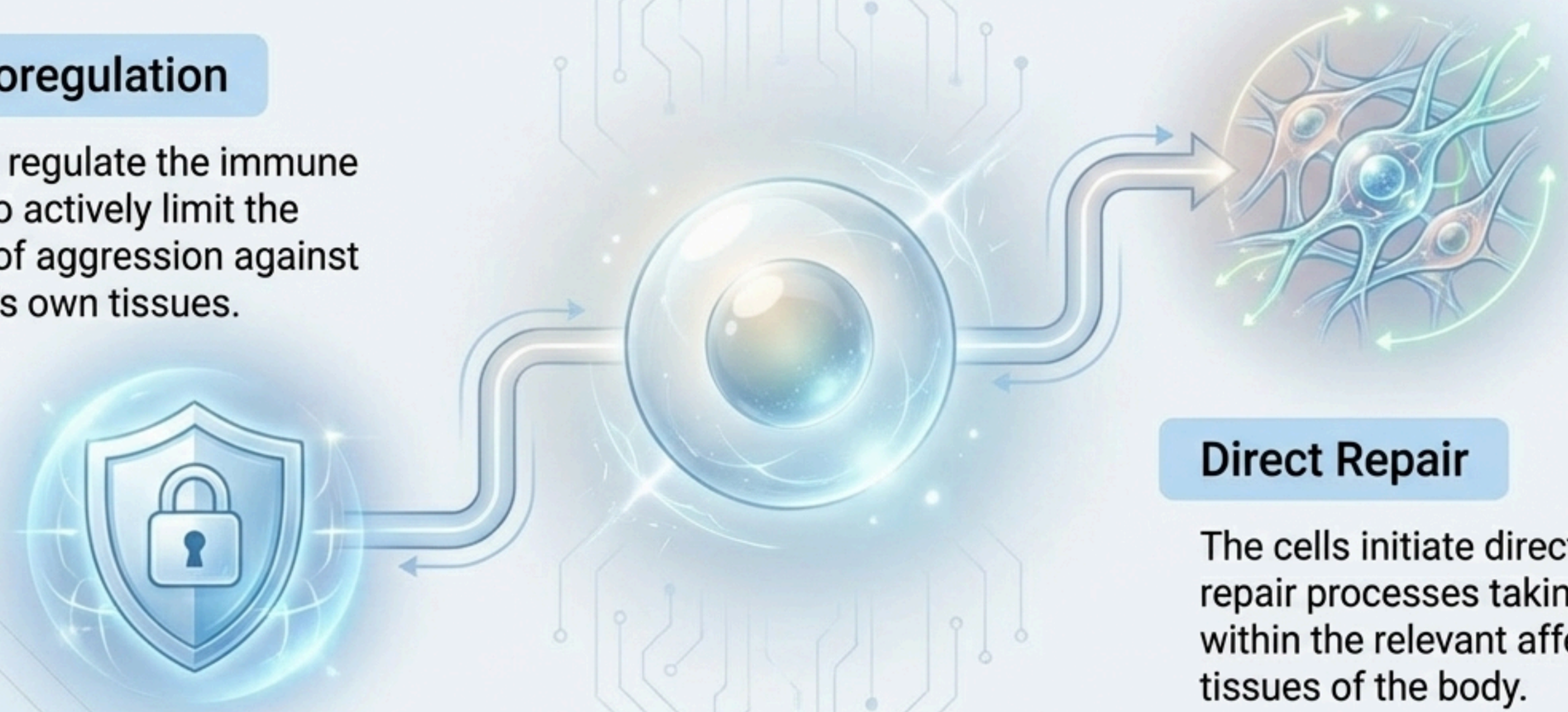
How WJ-MSCs operate within the pediatric nervous system

Immunoregulation

The cells regulate the immune system to actively limit the process of aggression against the body's own tissues.



Direct Repair

The cells initiate direct cellular repair processes taking place within the relevant affected tissues of the body.

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Patient eligibility and medical exclusion criteria

Inclusion Criteria	Absolute Exclusions
• Patients of both sexes. • Age range: 1 to 18 years old. • Diagnosed with a neurological disease lacking causal treatment or where current treatments have failed. • Obligation to use contraception during therapy (for females).	• Pregnancy, breastfeeding, or female infertility (risk to fetus). • Severe or acute organ damage. • Active infectious diseases (e.g., HIV, HBV, HCV, HPV). • Severe mental disorders or malignant neoplasms. • Unstable cardiovascular system. • Allergy to penicillin G.

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The highly regulated journey from donor tissue to patient infusion

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1. Collection & Rapid Transport

Cord tissue is placed in sterile saline and transported within 24 hours to the Polish Stem Cell Bank (PBKM).



2. Isolation & Culture

The Cell Engineering Lab (GIF Permit No. GIF-IW-400...) isolates tissue fragments and conducts in vitro culture to extract mesenchymal cells.



3. Testing & Cryopreservation

Portions are frozen to maintain continuity. Strict testing confirms cell count, viability, surface antigens, antigens, and microbiological safety.



4. Delivery to KLARA

Cells are transported to the KLARA Medical Center using specialized PBKM vehicles equipped with dedicated transport kits.



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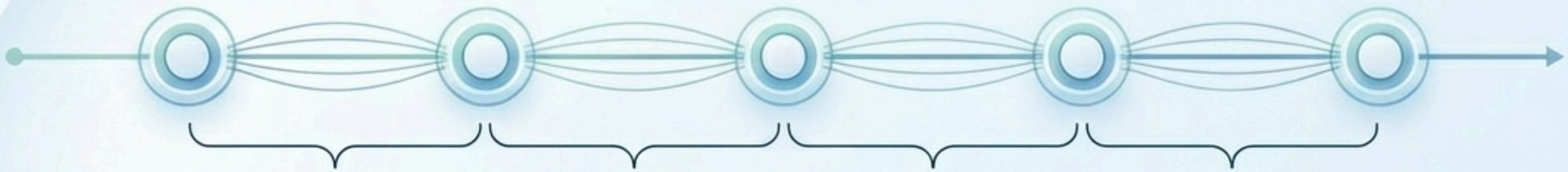
The three-year structured treatment protocol

Total: 15 Injections



1 Cycle = 5 Injections



Spaced exactly **4 to 6 weeks** apart

(Interval can be reduced to 2 weeks if approved by the evaluating medical team)

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Precision dosing and the bedside administration process

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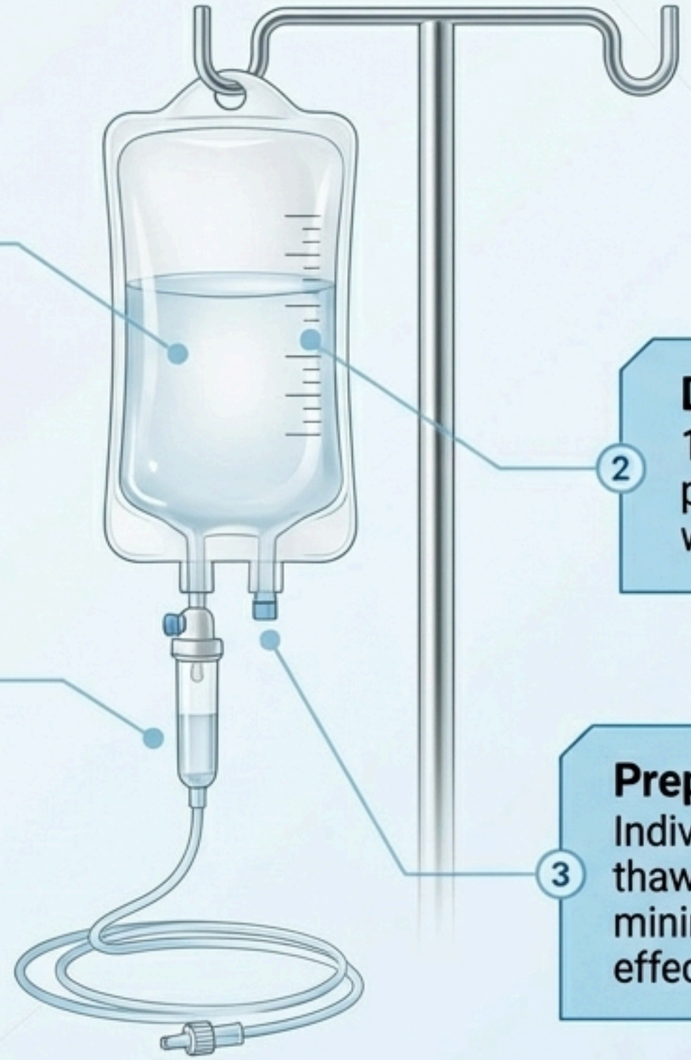
Volume & Method:
Exclusively administered via **intravenous** (IV) infusion due to necessary side-effect monitoring. The total volume never exceeds 6 ml.



Dosage:
1 to 2 million mesenchymal cells per kilogram of the patient's body weight (minimum dose: 1 million/kg).

No Rinsing Required:
The low admixture of DMSO undergoes standard decomposition in the liver, meaning the preparation does not need to be rinsed prior to infusion.

Preparation:
Individual doses containing DMSO are thawed directly at bedside. This minimizes positive-temperature toxic effects of the cryoprotectant.

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What to expect during a scheduled hospital visit

1. Clinical Baselines

Morning admission to the ward. Mandatory physical examination, neurological examination, and vital function monitoring.

2. Functional Assessments

GMFM test, gait kinetics examination, and muscle strength evaluation to track physical capabilities.

3. Specialized Monitoring

PEDI pediatric disability assessment questionnaire, spirometry (specifically for muscular dystrophy), and a self-administered patient questionnaire.

4. The Procedure

The actual MSC administration followed by immediate, dedicated adverse event assessment.

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Weighing expected therapeutic outcomes against potential risks

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Expected Benefits

The goal is at least a minimal improvement in clinical condition and minimal restoration of lost bodily functions. It is currently the only possible treatment for these diagnoses.



Potential Risks

Observed / Mild

Allergic reactions (rash, hives), temporary headaches, low-grade fever, neck stiffness, leg pain, fatigue, confusion, or difficulty walking for several hours.

Theoretical / Rare

Viral or bacterial transmission, DMSO poisoning, or acute post-transfusion respiratory failure.

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Financial logistics and strict funding guidelines

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Not Reimbursed: The MSC therapy is an experimental treatment and is strictly NOT reimbursed by the National Health Fund (NFZ).



Individualized Cost: Total costs are customized post-qualification, depending entirely on the specific neurological condition, the exact number of cells required, and the route of administration.



Strict Payment Rule: Patients and parents **CANNOT** pay out of pocket. Payment is exclusively accepted via a registered foundation or association. CM Klara provides full cost certificates to assist families in securing foundation funding.

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Initiating the qualification process for MSC therapy

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1. Gather Documentation

Collect the child's complete medical history featuring a formal diagnosis. Secure specific fresh laboratory results: Qualitative HCV RNA, anti-Hbs, and HIV.



2. Submit for Verification



Send the complete dossier to the medical center for the specialized medical team to conduct preliminary qualification and verification.

3. Hospitalization Scheduling



Upon successful verification, the medical team will reach out to schedule the initial morning admission and first MSC administration.

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