Cryopreserved human placental tissue (Stravix) for wound repair

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Lay summary

Cryopreserved human placental tissue is a new treatment to aid the healing of wounds that may reduce inflammation and scarring. Skin damage through cuts, burns or surgery are a source of discomfort, inflammation and scarring, and can also lead to infections. Cryopreserved human placental tissue includes molecules and materials expected to aid wound healing as well as living cells.

This briefing is based on information available at the time of research and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information.

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TARGET GROUP

- Surgical wounds: acute or chronic, with damaged or inadequate integument.

TECHNOLOGY

DESCRIPTION

Cryopreserved human placental tissue (Stravix) is a wound dressing containing umbilical amnion and Wharton’s jelly. It contains a mixture of extracellular matrix, growth factors and viable mesenchymal stem cells, fibroblasts and epithelial cells. Stravix is expected to provide an anti-adhesion, and anti-inflammatory barrier that may aid wound repair while reducing scarring. Stravix should be stored between -75°C to -85°C and used within 2 years.

Stravix is presented as an elastic 2x4cm or 3x6cm, 1-3mm thick membrane that is applied directly to the wound. The treatment duration has not been reported. Stravix does not currently have marketing authorisation for any indication.

INNOVATION and/or ADVANTAGES

If licensed, Stravix will offer an additional treatment option for patients with acute or chronic wounds.

DEVELOPER

Osiris Therapeutics.

PATIENT GROUP

BACKGROUND

The mechanism of dermal wound healing progresses over four broad phases:
1) Haemostasis – bleeding, blood vessel constriction, platelet aggregation and clotting, with leukocyte attraction.
2) Inflammation – localised vasodilation controlled by prostaglandins and other cell-derived and plasma derived mediators.
3) Granulation – connective tissue formation and angiogenesis creates healthy tissue, contracting the wound.
4) Epithelialisation – new skin cells proliferate on the wound edge, fully sealing the wound.

Open wounds may lead to significant fluid loss and are a potential source of infection. The healing process leads to a variable level of scarring, which may be painful or have inferior mechanical properties compared to undamaged tissue.

CLINICAL NEED and BURDEN OF DISEASE

The population likely to be eligible to receive Stravix could not be estimated from available published sources.
PATIENT PATHWAY

RELEVANT GUIDANCE

NICE Guidance

- NICE advice. The Versajet II hydrosurgery system for surgical debridement of acute and chronic wounds and burns (MIB1). February 2014.
- NICE medical technology guidance. The MIST Therapy system for the promotion of wound healing (MTG5). July 2011.

NHS England Policies and Guidance

- None identified

Other Guidance

- Wounds UK. Postoperative incision management. 2012³.

CURRENT TREATMENT OPTIONS

Surgical wounds are dressed dependent on the wound and stage of healing. Considerations for dressing choice include whether the wound is chronic or acute, the level of exudate, whether there is significant tissue loss and / or infection.

Examples of available wound dressings include⁵,⁶:

- Island dressings – absorbant, non-adherent pad with an adhesive cover for acute surgical incisions (low exudating wounds).
- Non-adherent moist (Tulle Gras dressing) – paraffin impregnated gauze for open wounds.
- Non-adherent dry – perforated plastic film attached to absorbent pad for wounds with moderate exudate, epidermal wounds.
- Calcium alginate – polysaccharide gel dressing for moderate to high exuding wounds, those with minor bleeding and various ulcers.
- Hydrocolloid (polyurethane film) – for burns and small abrasions.
- Silver dressings – containing silver for burns and infected wounds.
- Negative pressure wound therapy – foam sponge sealed onto wounds with vacuum applied for acute and chronic wounds.
- Autologous skin grafts – skin taken from a healthy portion of the patient’s body and grafted onto the wound area, used in the treatment of extensive wounds such as burns.
Human amnion/chorion membrane allografts have previously been developed for wound healing, but use dehydrated tissue that does not contain viable cells.  

**EFFICACY and SAFETY**

No clinical trials have been identified.

**ESTIMATED COST and IMPACT**

**COST**

The cost of Stravix is not yet known.

**IMPACT - SPECULATIVE**

**Impact on Patients and Carers**

- Reduced mortality/increased length of survival
- Reduced symptoms or disability
- Other
- No impact identified

**Impact on Health and Social Care Services**

- Increased use of existing services
- Decreased use of existing services
- Re-organisation of existing services
- Need for new services
- Other
- None identified

**Impact on Costs and Other Resource Use**

- Increased drug treatment costs
- Reduced drug treatment costs
- Other increase in costs:
- Other reduction in costs:
- Other: uncertain unit cost compared to existing treatments
- None identified

**Other Issues**

- Clinical uncertainty or other research question identified: there is currently a lack of available clinical evidence.
- None identified

**REFERENCES**

