

Recovery and survival of platelets in additive solution

Gepubliceerd: 25-03-2015 Laatste bijgewerkt: 15-05-2024

The recovery and survival of platelets stored in 3 different platelet additive solutions for 7 days is non inferior to the recovery and survival of platelets stored in plasma for 7 days

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24088

Bron

Nationaal Trial Register

Verkorte titel

RaSPAS study

Aandoening

Hemato oncologic disease; myelodysplastic syndrome; platelets; plasma; additive solution; recovery; survival

Ondersteuning

Primaire sponsor: Sanquin Bloedbank

Overige ondersteuning: nvt

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Platelet recovery in the study groups should be $\geq 67\%$ of platelets in plasma stored for 2-3

days.

Toelichting onderzoek

Achtergrond van het onderzoek

Platelets in plasma can be stored for at least 7 days under blood bank conditions with maintenance of in vitro and in vivo quality. The use of platelet additive solution (PAS) as replacement for storage in plasma is attractive, as PASs are associated with about 50% fewer allergic reactions post transfusion. Further, there is evidence that the newer generation PASs have much better capability of maintaining the platelet quality, and are thought to be at least equal to that in plasma. A number of alternative PASs are available (for example Composol, Intersol and SSP+); not only do they preserve the platelet function better, they also provide a margin in case safety technologies (like pathogen reduction methods) are applied that would potentially reduce platelet shelf life.

The objectives of this study is to determine the recovery and survival of platelet concentrates;

in the first phase, a comparison will be made for platelet concentrates in plasma stored for 2-3

days versus those stored for 6-7 days; in the second phase, platelet concentrates stored for 6-7

days in Composol, Intersol and SSP+ (in about a 35%-plasma/65%-PAS ratio) will be evaluated.

Doel van het onderzoek

The recovery and survival of platelets stored in 3 different platelet additive solutions for 7 days is non inferior to the recovery and survival of platelets stored in plasma for 7 days

Onderzoeksproduct en/of interventie

The standard of care in the Netherlands is 7 day storage of platelet concentrates in plasma or

in Intersol platelet additive solution (PAS). The intervention is that patients will receive platelet concentrates in newer PASs, stored for 6-7 days.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age $\geq$ 18 years.
- Expected to require at least one platelet transfusion.
- Signed informed consent.
- Are hospitalized.
- Clinically stable, i.e. no active bleeding, no fever, or other reasons for increased platelet consumption.
- Have acute leukemia or MDS.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Micro-angiopathic thrombocytopenia (TTP, HUS) and ITP.
- Bleeding $\geq$ grade 2 at time of inclusion.
- Transfusions within 1 week after ATG
- Known immunological refractoriness to platelet transfusions.
- HLA- and/or HPA-allo immunization and/or clinically relevant auto-antibodies.
- Indications to use platelet concentrates with specific characteristics/modifications.
- Pregnancy (or lactating).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	04-05-2015
Aantal proefpersonen:	0
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum: 25-03-2015
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41726
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4875
NTR-old	NTR5146
CCMO	NL49911.098.14
OMON	NL-OMON41726

Resultaten