**증례보고서(Case Report Form)**

|  |  |
| --- | --- |
| **Study Title** | **새로 진단된 간질폐질환을 동반한 한국인 류마티스관절염 환자에서 메토트렉세이트 유지 여부에 따른 임상 경과 비교:**  **전향적 관찰 연구** |

|  |  |
| --- | --- |
| Study No | KoNECT-RA-NIS-001 |
| Version | 1.0 |
| Institution |  |
| Principal Investigator |  |
| **Screening No.** |  |
| **Subject No.** |  |
| **Subject Initials** | |  |  |  | | --- | --- | --- | |  |  |  | |

**임상연구일정표**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Activity** | **방문 일정** | | | | | | |
|  | **스크리닝** | **베이스라인** |  |  |  |  |  |
|  | - 4주 | 0 | 12 ± 2주  (3개월) | 24 ± 4주  (6개월) | 52 ± 4주  (12개월) | 76 ± 4주  (18개월) | 104 ± 4주  (24개월) |
| 동의서 획득 | ✓ |  |  |  |  |  |  |
| 기초 정보 | ✓ |  |  |  |  |  |  |
| 포함/제외 기준 평가 | ✓ |  |  |  |  |  |  |
| 이전 RA/ILD 치료 내역 | ✓ |  |  |  |  |  |  |
| 류마티스관절염 치료  (MTX 유지 또는 중단) |  | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 병용 약물 확인 |  | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 호흡기 AE |  | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 일반 AE |  | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 폐 영상 평가(HRCT) |  | ✓ |  | ✓ | ✓ |  | ✓ |
| 폐기능(FVC, DLCO) 검사 |  | ✓ |  | ✓ | ✓ |  | ✓ |
| DAS28-ESR/CRP |  | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| ACR20/50/70 |  | ✓ |  | ✓ | ✓ | ✓ | ✓ |
| mTSS (X-rays of Hands and Feet) |  | ✓ |  | ✓ | ✓ |  | ✓ |
| PRO (HAQ-DI, VAS, mMRC) |  | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

**[ Screening ]**

**스크리닝 방문**

|  |  |
| --- | --- |
| **Screening No.** | ＿＿＿＿ |
| **Date of visit (yyyy/mm/dd)** | ＿＿＿＿/＿＿/＿＿ |

**동의서 취득**

|  |  |
| --- | --- |
| **Informed consent** | |
| Informed consent Date  (yyyy/mm/dd) | ＿＿＿＿/＿＿/＿＿ |
| Informed consent version | 1.0 |

**기초 정보 - 인구학적 정보**

|  |  |
| --- | --- |
| **Demographics** | |
| 출생연월 (yyyy/mm) | ＿＿＿＿/＿＿ |
| Age (자동계산) | ＿＿＿＿ |
| Sex | O Male O Female 🡪 If female, childbearing potential?  O Yes O No |
| Race | O Asian O White O Black/African American O Other ( ) |

**기초 정보 – 흡연, 음주력**

|  |  |
| --- | --- |
| **Substance use** | |
| 흡연 여부 | O 비흡연자 O (현재) 흡연자 O 과거 흡연자 |
| 흡연량(현재 또는 과거 흡연자) | 흡연기간 ＿＿년 (Ongoing? O Yes O No  🡪 If No, 마지막 흡연일 ＿＿＿＿/＿＿/＿＿)  흡연량 ＿＿ 개피/일 |
| 음주 여부 | O 비음주자 O (현재) 음주자 O 과거 음주자 |
| 음주량(현재 또는 과거 음주자) | 음주기간 ＿＿년 (Ongoing? O Yes O No  🡪 If No, 마지막 음주일 ＿＿＿＿/＿＿/＿＿)  음주종류 O 맥주 O 소주 O 와인 O 기타 ( )  음주량 ＿＿ /일 (단위 O 잔 O 병) |

**기초 정보 – 류마티스 관절염 병력**

|  |  |
| --- | --- |
| **RA disease history/status** | |
| Date of Initial diagnosis of RA | ＿＿＿＿/ ＿＿/ ＿＿ |
| Rheumatoid factor |  |
| anti-CCP |  |
|  |  |

**기초 정보 – 간질성 폐질환 병력**

|  |  |
| --- | --- |
| **Interstitial lung disease status** | |
| Date of Initial diagnosis of ILD | ＿＿＿＿/ ＿＿/ ＿＿ |
|  |  |
|  |  |
|  |  |

**현병력/과거력(수술력 포함)**

|  |  |
| --- | --- |
| **Medical history** | |
| Does the subject have any relevant medical history? | O Yes O No |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Number | Medical condition /  Surgery (행 추가 가능) | Start date  (yyyy/mm/dd) | Ongoing? | End date  (yyyy/mm/dd) |
| 1 |  | ＿＿＿＿/＿＿/＿＿ | O Yes O No | ＿＿＿＿/＿＿/＿＿ |
| 2 |  | ＿＿＿＿/＿＿/＿＿ | O Yes O No | ＿＿＿＿/＿＿/＿＿ |
| 3 |  | ＿＿＿＿/＿＿/＿＿ | O Yes O No | ＿＿＿＿/＿＿/＿＿ |
| 4 |  | ＿＿＿＿/＿＿/＿＿ | O Yes O No | ＿＿＿＿/＿＿/＿＿ |
| 5 |  | ＿＿＿＿/＿＿/＿＿ | O Yes O No | ＿＿＿＿/＿＿/＿＿ |

**이전 류마티스관절염 치료력**

|  |  |
| --- | --- |
| **Previous treatment for RA** | □Yes → if yes, specify below. □No |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Number | Name | Dose  /Regimen | Route | Indication | Start date  (yyyy/mm/dd) | Ongoing? | End date  (yyyy/mm/dd) |
| 1 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 2 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 3 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 4 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 5 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |

**이전 간질폐질환 치료력**

|  |  |
| --- | --- |
| **Previous treatment for ILD** | □Yes → if yes, specify below. □No |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Number | Name | Dose  /Regimen | Route | Indication | Start date  (yyyy/mm/dd) | Ongoing? | End date  (yyyy/mm/dd) |
| 1 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 2 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 3 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 4 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 5 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |

**선정제외기준 검토/적격성 평가**

|  |  |  |
| --- | --- | --- |
| **Inclusion Criteria** | | |
| 시험대상자는 아래 선정기준을 모두 만족해야 한다. | | |
| 1. 나이 만 19세 이상 |  | □ Yes □ No |
| 2. 연구 절차에 동의하고, 서면 동의를 제공할 수 있는 자. |  | □ Yes □ No |
| 3. 2010 ACR/EULAR 또는 1987 ACR 기준을 충족하는 류마티스관절염 환자. |  | □ Yes □ No |
| 4. 연구 등록일로부터 OO개월 이내 HRCT상 ILD 진단 환자. |  | □ Yes □ No |
| 5. 연구 등록일로부터 OO개월 (예: 3개월, 6개월) 이상 MTX단독 또는 MTX 포함 요법으로 치료를 받았던 환자. |  | □ Yes □ No |

|  |  |
| --- | --- |
| **Exclusion Criteria** |  |
| 제외기준에 하나 이상의 '예'가 있을 경우 시험에서 제외시킨다. |  |
| 1. ILD 진단 시 중대한 폐 기능 장애로 인해 MTX 사용이 명확히 금기인 환자. | □ Yes □ No |
| 2. 폐 기능 검사(Pulmonary Function Test, PFT)가 불가능한 환자. | □ Yes □ No |
| 3. 이전에 생물학적 제제(biologics)를 투여 받은 이력이 있는 환자 (Tumor Necrosis Factor, TNF 억제제 포함). | □ Yes □ No |
| 4. 항섬유화제(피르페니돈, 닌테다닙 등) 사용 전력이 있는 환자. | □ Yes □ No |
| 5. 연구 등록일로부터 5년 이내에 악성종양을 진단받은 환자. | □ Yes □ No |
| 6. 연구 등록일로부터 5년 이내에 방사선 치료력이 있는 환자. | □ Yes □ No |
| 7. 스크리닝 시점 기준으로 다음과 같은 심혈관계 질환이 있는 환자  • 6개월 이내에 심근경색증 또는 불안정 협심증, 뇌졸중 또는 일과성 허혈성 발작(transient ischemic attack)  • 뉴욕심장협회(New York Heart Association, NYHA) class III 이상의 울혈성 심부전 | □ Yes □ No |
| 8. 급성 또는 중증 감염 환자 | □ Yes □ No |
| 9. 임신 또는 수유 중인 환자이거나, 연구 기간 중 임신을 계획 중인 환자. | □ Yes □ No |
| 10. 스크리닝 전 4주 이내에 임상시험용의약품을 투여 받은 환자 (시험약을 투여 받지 않았거나 비중재 관찰연구에 참여한 경우에는 등록 가능) | □ Yes □ No |
| 11. 이 외 사유로 연구자가 판단하기에 본 임상연구 참여가 부적절한 환자 | □ Yes □ No |

**Screening failure**

Is the subject a screen failure? □ Yes □ No

If Yes, Screen failure date (YYYY/MM/DD)

**[ Baseline ]**

**베이스라인 방문**

|  |  |
| --- | --- |
| **Subject No.** | ＿＿＿＿ |
| **Date of visit (yyyy/mm/dd)** | ＿＿＿＿/＿＿/＿＿ |

**류마티스관절염 치료**

Is the subject continuing methotrexate treatment at this visit? □ Yes □ No

Specify the current treatment for RA;

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Number | Name | Dose  /Regimen | Route | Indication | Start date  (yyyy/mm/dd) | Ongoing? | End date  (yyyy/mm/dd) |
| 1 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 2 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 3 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 4 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 5 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |

**이상사례/병용약물**

Were any AE (including pulmonary AE) experienced since last visit? □ Yes □ No

If yes, AE should be reported in the Adverse Event form as appropriate.

Were any new concomitant medications given or change since last visit? □ Yes □ No

If yes, concomitant medications should be updated or reported in the concomitant medications form as appropriate.

**폐 영상 평가 (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Imaging modality | Date of assessment  (yyyy/mm/dd) | Findings (자유 기술) |
| 1 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 2 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 3 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 4 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**폐기능검사 (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Test method | Date of assessment  (yyyy/mm/dd) | Findings (자유 기술) |
| 1 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 2 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 3 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 4 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**질병 활성도 평가 (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Test method | Date of assessment  (yyyy/mm/dd) | Result |
| 1 | **DAS28-CRP** | ＿＿＿＿/＿＿/＿＿ |  |
| 2 | **ACR 20** | ＿＿＿＿/＿＿/＿＿ |  |
| 3 | **…** | ＿＿＿＿/＿＿/＿＿ |  |
| 4 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**mTSS (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Test method | Date of assessment  (yyyy/mm/dd) | Findings (자유 기술) |
| 1 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 2 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 3 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 4 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**삶의 질 평가 (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Questionnaire | Date of assessment  (yyyy/mm/dd) | Result |
| 1 | **HAQ-DI** | ＿＿＿＿/＿＿/＿＿ |  |
| 2 | **VAS** | ＿＿＿＿/＿＿/＿＿ |  |
| 3 | **mMRC** | ＿＿＿＿/＿＿/＿＿ |  |
| 4 | **…** | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**[Follow-up visits]**

**Visit Information**

Was the visit performed? □ Yes □ No

If Yes, Date of visit (YYYY/MM/DD) ＿＿＿＿ / ＿＿ / ＿＿

If No, reason not performed

**류마티스관절염 치료**

Since the last visit, has there been any change in the treatment for RA? □ Yes □ No

Specify the current treatment for RA;

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Number | Name | Dose  /Regimen | Route | Indication | Start date  (yyyy/mm/dd) | Ongoing? | End date  (yyyy/mm/dd) |
| 1 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 2 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 3 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 4 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |
| 5 |  |  |  |  | ＿＿＿＿/＿＿/＿＿ | O | ＿＿＿＿/＿＿/＿＿ |

**이상사례/병용약물**

Were any AE (including pulmonary AE) experienced since last visit? □ Yes □ No

If yes, AE should be reported in the Adverse Event form as appropriate.

Were any new concomitant medications given or change since last visit? □ Yes □ No

If yes, concomitant medications should be updated or reported in the concomitant medications form as appropriate.

**폐 영상 평가 (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Imaging modality | Date of assessment  (yyyy/mm/dd) | Findings (자유 기술) |
| 1 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 2 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 3 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 4 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**폐기능검사 (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Test method | Date of assessment  (yyyy/mm/dd) | Findings (자유 기술) |
| 1 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 2 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 3 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 4 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**질병 활성도 평가 (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Test method | Date of assessment  (yyyy/mm/dd) | Result |
| 1 | **DAS28-CRP** | ＿＿＿＿/＿＿/＿＿ |  |
| 2 | **ACR 20** | ＿＿＿＿/＿＿/＿＿ |  |
| 3 | **…** | ＿＿＿＿/＿＿/＿＿ |  |
| 4 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**mTSS (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Test method | Date of assessment  (yyyy/mm/dd) | Findings (자유 기술) |
| 1 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 2 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 3 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 4 |  | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**삶의 질 평가 (**□ Not Done**)**

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Questionnaire | Date of assessment  (yyyy/mm/dd) | Result |
| 1 | **HAQ-DI** | ＿＿＿＿/＿＿/＿＿ |  |
| 2 | **VAS** | ＿＿＿＿/＿＿/＿＿ |  |
| 3 | **mMRC** | ＿＿＿＿/＿＿/＿＿ |  |
| 4 | **…** | ＿＿＿＿/＿＿/＿＿ |  |
| 5 |  | ＿＿＿＿/＿＿/＿＿ |  |

**[End of Study]**

Did the subject discontinue the study? □ Yes □ No

Date of disposition (YYYY/MM/DD) ＿＿＿＿ / ＿＿ / ＿＿

If the subject discontinued this study, provide the primary reason

□ Withdrawal of consent □ Investigator’s and Sponsor’s Decision □ Lost to follow-up

□ Pregnancy □ Death □ Termination of study by sponsor □ Other (specify)

**[Adverse Event log]**

Were any Adverse Events experienced? □ Yes □ No

|  |  |  |  |
| --- | --- | --- | --- |
|  | Events ( ) | Events ( ) | Events ( ) |
| Adverse Event |  |  |  |
| Onset Date | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  |  | / |  |  |   Day Month Year | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  |  | / |  |  |   Day Month Year | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  |  | / |  |  |   Day Month Year |
| Onset Time | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | : |  |  |   Hour Minutes | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | : |  |  |   Hour Minutes | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | : |  |  |   Hour Minutes |
| Stop date | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  |  | / |  |  |   Day Month Year | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  |  | / |  |  |   Day Month Year | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  |  | / |  |  |   Day Month Year |
| Stop time | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | : |  |  |   Hour Minutes | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | : |  |  |   Hour Minutes | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | : |  |  |   Hour Minutes |
| Grade1) |  |  |  |
| Outcome2) |  |  |  |
| SAE3) |  |  |  |
| Causality relationship to EVR4) |  |  |  |
| Action taken with EVR5) |  |  |  |
| Action taken6) |  |  |  |
| 1) Severity: Grade 1= Mild, Grade 2= Moderate, Grade 3= Severe, Grade 4= Life-Threatening, Grade 5= Fatal  2) 결과[outcome]: 1= Recovered/Resolved 2 = Recovered/Resolved *with Sequelae* 3 = Recovering/Resolving  4 = 이상반응지속(조치없음) 5 = 이상반응지속(조치지속, 사망, 추적관찰 실패)  3) 경중도[seriousness]: 1 = Yes, 2 = No  4) 인과관계[relatedness]: 1 = not related 2 = related  5) 취해진 조치[action taken] : 0 = 취해진 조치 없음 [no action taken]  1 = 비약물치료 [non-drug therapy given]  2 = 치료약물 병용투여 [concomitant medication taken]  3 = 입원/입원기간의 연장 [hospitalization / prolonged hospitalization]  4 = 임상시험 중단 [withdrawal from this study]  6) Action taken with EVR: .0 = None 1= Dose Reduced 3= Interrupted 4= Withdrawn | | | |

**[Concomitant medication log]**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Generic name | Strength per dose | Frequency per day | \*Route | Reason for  medication | 시작일  (Date of start) | 종료일  (Date of end) | Ongoing |
|  |  |  |  |  | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | **/** |  |  |  | **/** |  |  |   Day Month Year | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | **/** |  |  |  | **/** |  |  |   Day Month Year | □ |
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\* IV.(IntraVenous), IM.(IntraMuscular), PO.(PerOral), SC.(SubCutaneous),SL.(SubLingual), etc.